The relationship between left ventricular systolic function and congestive heart failure diagnosed by clinical criteria

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ABSTRACT There is no uniformly accepted clinical definition for congestive heart failure (CHF), although criteria have been published by various groups. There is also no reference standard for CHF, although left ventricular ejection fraction (LVEF) gives a quantitative assessment of systolic function and is useful in predicting prognosis. To determine the relationship between LVEF and clinically diagnosed CHF, we compared resting LVEF determined by radionuclide ventriculography with diagnosis of CHF by clinical criteria in 407 patients, based on clinical data collected by a cardiology fellow. Of 153 patients with a low LVEF (≤0.40), 30 (20%) met none of the criteria for CHF. Conversely, of 204 patients with normal LVEF (≥0.50), 105 (51%) met at least one of the criteria. We conclude that different criteria for CHF will have varying utility depending on the population being examined, and that a combination of clinical features and an objective measure of cardiac performance is needed to diagnose CHF.


CONGESTIVE HEART FAILURE is among the most frequently encountered cardiac diagnoses. Prevalence of congestive heart failure is estimated to be 1% in the United States, and Framingham data gives an incidence rate of about 2 per 1000 persons per year. Only 50% of patients diagnosed as having congestive heart failure survive for 5 years. It also has major impact in terms of morbidity and hospitalization; among elderly patients, it is the most common medical indication for hospitalization.

Epidemiologic studies in congestive heart failure have been hampered by the lack of uniform diagnostic criteria, relying instead on physician diagnosis of the disease. The Framingham Study created clinical criteria for diagnosing congestive heart failure (table 1); however, these criteria have never been validated against a reference standard. A study performed at Duke derived another set of clinical criteria for congestive heart failure by a multivariate analysis of clinical variables against left ventricular end-diastolic pressure greater than 15 mm Hg in patients referred for cardiac catheterization with anatomically confirmed coronary artery disease. The criteria generated by this study were the presence of either an S_3 on examination or cardiomegaly on the chest x-ray (cardiotoracic ratio >0.48). A third group in Boston used clinical judgment to derive a set of diagnostic criteria (table 2), and then validated these against a pulmonary capillary wedge pressure greater than 12 mm Hg in patients undergoing nonemergency right heart catheterization.

To determine the relationship between the clinical diagnosis of congestive heart failure and objective measurement of systolic cardiac function, we compared the diagnosis of congestive heart failure, as determined by applying three different rating scales, with resting left ventricular ejection fraction, as measured by radionuclide wall motion studies. Although not a reference standard for the diagnosis of congestive heart failure per se, resting left ventricular ejection fraction has clinical significance as the most important predictor of prognosis in patients with coronary heart disease. It also can identify the subgroup of patients...
TABLE 1
Framingham criteria for congestive heart failure

<table>
<thead>
<tr>
<th>Major criteria</th>
<th>Point value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paroxysmal nocturnal dyspnea or orthopnea</td>
<td>4</td>
</tr>
<tr>
<td>Neck-vein distention</td>
<td>4</td>
</tr>
<tr>
<td>Rales</td>
<td>4</td>
</tr>
<tr>
<td>Cardiomegaly</td>
<td>3</td>
</tr>
<tr>
<td>Acute pulmonary edema</td>
<td>2</td>
</tr>
<tr>
<td>S3 gallop</td>
<td>2</td>
</tr>
<tr>
<td>Increased venous pressure &gt;16 cm of water</td>
<td>2</td>
</tr>
<tr>
<td>Circulation time &gt;25 sec</td>
<td>2</td>
</tr>
<tr>
<td>Hepatomegaly</td>
<td>1</td>
</tr>
<tr>
<td>Pleural effusion</td>
<td>1</td>
</tr>
<tr>
<td>Vital capacity decreased 1/3 from maximum</td>
<td>1</td>
</tr>
<tr>
<td>Tachycardia (rate of &gt;120/min)</td>
<td>1</td>
</tr>
</tbody>
</table>

For establishing a definite diagnosis of congestive heart failure in this study, two major or one major and two minor criteria had to be present concurrently.

with congestive heart failure who have normal systolic function, an important pathophysiologic mechanism that may require a different therapeutic approach.7

Materials and methods

Between July 1982 and June 1983, a study to evaluate the efficacy of cardiovascular nuclear medicine studies (CVNMS) was conducted at the Albert Einstein College of Medicine affiliated hospitals. The design of this study has been described in detail previously.8 During this period, radionuclide evaluation was performed on 2321 patients who were not on cardiotoxic drugs. Physicians referring patients for CVNMS were required to complete a form before the test, specifying reason for the test, suspected heart disease, and predicted outcome. There were 1272 patients who underwent a standardized clinical assessment by a cardiologist fellow immediately before the nuclear scan as part of the CVNMS efficacy study. These patients were similar to those not examined by a study fellow with regard to reason for referral for the CVNMS and CVNMS results.

There were 596 patients referred for exercise study, and 676 for resting radionuclide ventriculograms. We selected only those patients who were referred for resting wall motion study, since these patients are more likely to represent a population with suspected congestive heart failure than with suspected ischemia. Based on data from the standardized referral form, the referring physician suspected congestive heart failure in 66% of subjects referred for resting study, but in only 6% of those referred for exercise study. Among the resting study subjects, there were 407 for whom a complete history, physical data, and a chest x-ray were obtained, and in whom the wall motion study was technically adequate.

The Framingham and Duke scales are dichotomous with respect to the presence or absence of congestive heart failure, while the Boston scale classifies patients as having definite, possible, or unlikely congestive heart failure. Some modifications of the grading criteria had to be made for this study. Specifically, although cardiomegaly was a factor in all three scales, Framingham did not specify how cardiomegaly would be defined, the Duke scale required a cardiothoracic ratio on chest x-ray greater than 0.48, and the Boston scale required a ratio greater than or equal to 0.50. For our analysis, we accepted a radiologist’s reading of cardiomegaly on the chest x-ray, since explicit measures of cardiothoracic ratio were not in our data base. The Boston scale gave different point counts to “dyspnea on climbing,” “dyspnea on walking on level,” and “rest dyspnea”; we equated these with dyspnea on “extreme exertion,” “minimal/moderate exertion,” or “at rest,” respectively, as recorded during our clinical assessment. In adapting the Framingham scale, we excluded criteria that were either not entered in our data base (namely, night cough or weight loss) or that are not routinely used in the clinical diagnosis of congestive heart failure (venous pressure, circulation time, or vital capacity).

Once patients were classified, the groups were compared with respect to ejection fraction, by mean ejection fraction and by proportion with ejection fraction of 0.40 or less, 0.41 to 0.49, and 0.50 or more. These levels were selected to separate equivocal levels of ejection fraction from those that are more clearly normal or abnormal. We also related the clinical classification with patient’s medication history.

Ejection fractions are reported as the mean ± SEM. Statistical analysis was performed with computer software from Statistical Analysis Systems (SAS), with the use of analysis of variance to compare group means for continuous data, and where

TABLE 2
Boston criteria for congestive heart failure

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Point value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category I: History</td>
<td></td>
</tr>
<tr>
<td>Rest dyspnea</td>
<td>4</td>
</tr>
<tr>
<td>Orthopnea</td>
<td>4</td>
</tr>
<tr>
<td>Paroxysmal nocturnal dyspnea</td>
<td>3</td>
</tr>
<tr>
<td>Dyspnea on walking on level</td>
<td>2</td>
</tr>
<tr>
<td>Dyspnea on climbing</td>
<td>1</td>
</tr>
<tr>
<td>Category II: Physical examination</td>
<td></td>
</tr>
<tr>
<td>Heart rate abnormality</td>
<td>1–2</td>
</tr>
<tr>
<td>(if 91–110 beats/min, 1 point; if &gt;110 beats/min, 2 points)</td>
<td>2–3</td>
</tr>
<tr>
<td>Jugular-venous pressure elevation</td>
<td></td>
</tr>
<tr>
<td>(if &gt;6 cm H2O, 2 points; if &gt;6 cm H2O plus hepatomegaly or edema, 3 points)</td>
<td>1–2</td>
</tr>
<tr>
<td>Lung crackles</td>
<td></td>
</tr>
<tr>
<td>(if basilar, 1 point; if more than basilar, 2 points)</td>
<td>3</td>
</tr>
<tr>
<td>Wheezing</td>
<td>3</td>
</tr>
<tr>
<td>Third heart sound</td>
<td>3</td>
</tr>
<tr>
<td>Category III: Chest radiography</td>
<td></td>
</tr>
<tr>
<td>Alveolar pulmonary edema</td>
<td>4</td>
</tr>
<tr>
<td>Interstitial pulmonary edema</td>
<td>3</td>
</tr>
<tr>
<td>Bilateral pleural effusions</td>
<td>3</td>
</tr>
<tr>
<td>Cardiothoracic ratio &gt;0.50</td>
<td>3</td>
</tr>
<tr>
<td>(posteroanterior projection)</td>
<td></td>
</tr>
<tr>
<td>Upper zone flow redistribution</td>
<td>2</td>
</tr>
</tbody>
</table>

*No more than 4 points were allowed from each of three categories, and hence the composite score, the sum of the subtotal from each category, had a maximum possible of 12 points. The diagnosis of heart failure was 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.
appropriate, the Scheffe test for multiple comparisons. Categorical data were evaluated by the use of chi-square tests. Values of \( p < .05 \) were considered statistically significant. Interscale agreement was measured by means of the kappa statistic, which takes observed agreement and corrects for agreement expected by chance alone.⁵

**Results**

Of our 407 patients, 91% were in-patients at the time of CVNMS. The mean age was 64 years, with 34% age 70 or greater. Sixty-five percent of the study subjects were men. The reason for the test, as given by the referring physician, was to determine severity of disease in 61%, to confirm the presence of disease in 25%, to confirm absence of disease in 6%, and in 8% to monitor therapy.

**Ejection fraction.** For the total group, the mean left ventricular ejection fraction was 0.49, with a left ventricular ejection fraction less than 0.50 in 204 (50%). Patients classified as having congestive heart failure by any of the scoring systems had significantly lower mean left ventricular ejection fractions when compared with those classified as not having congestive heart failure. Mean left ventricular ejection fraction for patients with congestive heart failure classified as present or absent according to the Framingham criteria was 0.45 ± 0.018 vs 0.53 ± 0.014 (\( p < .001 \)), and according to the Duke criteria 0.43 ± 0.015 vs 0.58 ± 0.016 (\( p < .0001 \)). The Boston scale classified patients as having definite, possible, or unlikely congestive heart failure; mean left ventricular ejection fraction in these patients was 0.41 ± 0.021 vs 0.51 ± 0.020 vs 0.55 ± 0.016, respectively (\( p < .0001 \)). The Scheffe test shows the significant difference to lie between those classified as having “definite congestive heart failure” and those with “possible or unlikely congestive heart failure.” Therefore, in the following discussion we will refer to the “definite” group as having congestive heart failure, and those classified as “possible or unlikely congestive heart failure” as not having congestive heart failure.

To determine the relationship between clinical classification of congestive heart failure and resting left ventricular ejection fraction, predetermined levels of left ventricular ejection fraction were used to classify patients into three distinct groups: low left ventricular ejection fraction (≤ 0.40), borderline (0.41 to 0.49), and normal left ventricular ejection fraction (≥ 0.50) (table 3). The data indicate significant associations on all three scales, with patients classified as having congestive heart failure more likely to have a low ejection fraction. Sensitivity and specificity of clinical diagnosis was calculated, setting left ventricular ejection fraction of 0.40 or less as the reference standard for clinically or prognostically important left ventricular dysfunction (table 3).

**Comparison of criteria.** We compared patients’ ratings among the various scales with results summarized in figure 1. We found that in patients with normal left ventricular ejection fraction (≥ 0.50) over half had congestive heart failure diagnosed by at least one of the criteria. Conversely, among subjects with low left ventricular ejection fraction (≤ 0.40), 20% met none of the criteria for congestive heart failure.

Concordance among the three scales was measured by calculation of the kappa statistic. The value of kappa was 0.38 comparing Duke with Boston, 0.52 comparing Duke with Framingham, and 0.67 comparing Framingham with Boston criteria. These values show an interscale agreement that is fair, moderate, and substantial, respectively.¹⁰

**Medication use.** It was found that substantial proportions of those subjects who did meet criteria for congestive heart failure were on β-blocking drugs (12% to 20%) (table 4). In addition, of those subject not meet-

**TABLE 3**

<table>
<thead>
<tr>
<th>LVEF category <a href="n">%</a></th>
<th>Framingham</th>
<th>Study</th>
<th>Duke</th>
<th>Boston</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 40</td>
<td>50 (96)</td>
<td>+</td>
<td>112</td>
<td>58 (76)</td>
</tr>
<tr>
<td>41-49</td>
<td>10 (19)</td>
<td>-</td>
<td>31</td>
<td>11 (19)</td>
</tr>
<tr>
<td>≥ 50</td>
<td>40 (76)</td>
<td>-</td>
<td>85</td>
<td>45 (45)</td>
</tr>
<tr>
<td>Sensitivity*</td>
<td>0.63</td>
<td>0.73</td>
<td>0.50</td>
<td></td>
</tr>
<tr>
<td>Specificity*</td>
<td>0.63</td>
<td>0.54</td>
<td>0.78</td>
<td></td>
</tr>
</tbody>
</table>

+ = CHF present by criteria; - = CHF absent by criteria.
*Compared with LVEF ≤ 40%.
ing criteria for congestive heart failure, about a third (31% to 36%) were being treated with digoxin. Similar results were found for patients without systolic dysfunction on nuclear scan: of subjects with normal left ventricular ejection fraction (≥0.50), 34% were being treated with digoxin, compared with 55% of those with low ejection fraction (<0.50).

**Discussion**

Our study indicates that although each of the three clinical scales identified patients with significantly lower ejection fractions, the three scales have varying sensitivities and specificities and could be expected to have different utilities depending on the goals of diagnosis (e.g., prognostication vs ruling out disease) and on the population being examined (e.g., high vs low prevalence of disease).

Evaluating the clinical diagnosis of congestive heart failure presents special problems due to the lack of accepted diagnostic criteria. Indeed, none of the three sets of criteria used in the present study is in wide use. In addition, there is not technologic reference standard for the diagnosis of heart failure. For example, pressure measurements (pulmonary capillary wedge pressure, left ventricular end-diastolic pressure) are not widely applicable. These measurements are extremely sensitive to therapeutic intervention, and may be normal despite severe ventricular dysfunction. Echocardiographic measurements are not easily quantified reproducibly, although the use of computer technologies is improving this situation. Nuclear studies provide a more quantifiable measure of cardiac function, but the resting left ventricular ejection fraction does not relate linearly to exercise capacity. Also, none of the measurements has a well-accepted cutoff level for "normal." For example, clinical trials in congestive heart failure use varying entry criteria of left ventricular ejection fraction, ranging from 0.30 to 0.49. In effect, then, a study of clinical criteria for congestive heart failure involves evaluating not only the criteria themselves but also the reference standard used.

Despite its usefulness in predicting prognosis, the major shortcoming of the left ventricular ejection fraction is its inability to identify diastolic dysfunction. The mechanism of diastolic dysfunction has been receiving increased attention, especially among the elderly. Given the high prevalence of elderly subjects in our study, it is possible that some of our subjects with clinical congestive heart failure had abnormalities in diastolic function, which we did not measure. In a previous study of patients with clinically diagnosed congestive heart failure (confirmed by a modification of the Boston criteria) referred for nuclear study, Soufer et al. found that 42% had intact systolic function (defined as left ventricular ejection fraction ≥0.45). This estimate is similar to that of Dougherty et al. (36%) and to our own (34% to 40%) (table 3). Of 58 such patients, 38% had diastolic dysfunction (defined as peak filling rate <2.5 end-diastolic volumes/sec), and an additional 24% had "probable diastolic dysfunction" (peak filling rate 2.5 to 3.0 end-diastolic volumes/sec). Objective measurement of diastolic function is not routinely obtained on radionuclide angiography, and even if available, would leave unexplained between 38% and 62% of patients with clinical congestive heart failure and normal systolic function. This implies that clinical judgment provides information about congestive heart failure that cannot be obtained from a nuclear scan.

Conversely, in our study, 23% to 28% of subjects

**TABLE 4**

<table>
<thead>
<tr>
<th>Drug therapy and clinical classification of congestive heart failure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Study</td>
</tr>
<tr>
<td>Framingham</td>
</tr>
<tr>
<td>Duke</td>
</tr>
<tr>
<td>Boston</td>
</tr>
<tr>
<td>Treated with [%/(n)]</td>
</tr>
<tr>
<td>+</td>
</tr>
<tr>
<td>β-Blocker</td>
</tr>
<tr>
<td>Diuretic</td>
</tr>
<tr>
<td>Digoxin</td>
</tr>
</tbody>
</table>

+ = CHF present by criteria; − = CHF absent by criteria.
classified as not having congestive heart failure had
depressed left ventricular ejection fractions (<0.40).
In fact, of all patients with clearly low left ventricular
ejection fractions, 20% were not diagnosed by any of
the three sets of clinical criteria (figure 1). Since a left
ventricular ejection fraction of 0.40 or less is generally
accepted as abnormal, this indicates that an objective
measure of left ventricular ejection fraction gives more
information than can be obtained by clinical evaluation
alone.

There are several limitations that must be considered
in interpreting these data. The first is the population
studied, which was a referral population with a high
prevalence of cardiac disease. History of hypertension
was present in 53%, 37% had a confirmed history of
prior myocardial infarction, and 49% had typical
angina. Although our study population is subject to a
referral filter bias, the noninvasive nature of the pro-
cedure would make our sample more representative of
patients with suspected congestive heart failure in clin-
ic practice than were the catheterized populations
previously studied.4, 5

Another limitation was the need to categorize patients
according to congestive heart failure criteria
through the retrospective application of a data base that
was not designed to answer this question. The problems
were minor in categorizing subjects on the Duke and
Boston criteria, involving simply substituting radiologist’s
reading of cardiomegaly for a specific value of
cardiothoracic ratio, and applying slightly different
terminology in the assessment of dyspnea. This lim-
itation was more serious with regard to the Framingham
criteria, where entire major and minor criteria had to
be eliminated, such as circulation time and vital capac-
ity. Inclusion of other criteria, however, could only
serve to diagnose more subjects as having congestive
heart failure. This might increase sensitivity, but at the
probable expense of a loss of specificity from the values
we derived of 0.63 and 0.63, respectively.

The effect of drug therapy in this population is dif-
cult to assess. Large proportions of the subjects were
taking medications such as digoxin (45%), diuretics
(61%), and ß-blockers (26%) (table 4). The impact of
drug therapy on left ventricular ejection fraction is
unclear in previous reports. For instance, there are two
randomized double-blind placebo controlled crossover
studies of digoxin that measured systolic left ventric-
ular function. Fleg et al.18 found no clinical response
to digoxin, but did show a small but statistically sig-
ificant rise in echocardiographically determined
velocity of circumferential fiber shortening with digo-
xin (0.90 circ/sec) compared with placebo (0.82
circ/sec) (p < .05). Conversely, Lee et al.19 found
clinical benefit with digoxin use, but no change in
resting radionuclide left ventricular ejection fraction
with digoxin (0.30) compared with placebo (0.29)
(p = .49). In a study of digoxin use after myocardial
infarction there was a statistically significant but clin-
ically insignificant rise in left ventricular ejection frac-
tion with digoxin use (0.29 ± 0.09 vs 0.33 ± 0.11,
p < .03).20 A study of propranolol showed no effect on
resting left ventricular ejection fraction in normal sub-
jects or in patients with coronary artery disease.21

Our data indicate that many subjects without con-
gestive heart failure by clinical criteria are being treated
with digoxin. This finding is consistent with those of
Carlson et al.5 who devised the Boston criteria. How-
ever, some of our subjects received digoxin for indica-
tions other than congestive heart failure. For exam-
ple, of 183 subjects taking digoxin, 27 had atrial
fibrillation or flutter (15%), compared with seven of
224 subjects not taking digoxin (3%). Significant left
ventricular dysfunction frequently coexisted with the
arrhythmia: 13 of the 27 subjects (48%) with atrial
arrhythmias on digoxin had a left ventricular ejection
fraction of 0.40 or less. The use of digoxin for atrial
arrhythmias would not account for the fact that only 84
of 183 subjects taking digoxin in our study (46%) met
the Boston criteria for congestive heart failure.

There are no uniformly accepted criteria for the
diagnosis of congestive heart failure, and there is no
“gold standard” for the diagnosis. The inability of
resting left ventricular ejection fraction to serve this
function has been well demonstrated.7, 14 We do not
suggest that our data can be used to validate clinical
criteria with left ventricular ejection fraction as a gold
standard. Rather, they indicate that a combination of
clinical diagnosis and an objective measure of cardiac
performance is necessary to definitively diagnose con-
gestive heart failure, since each provides information
not available from the other.

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and Ms. Sheila Reyes for the preparation of the manuscript.

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