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Opportunities for Improvement in the Diagnosis and Treatment of Heart Failure

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Summary

Background: Improved treatment of congestive heart failure (CHF) can slow disease progression, promote clinical stability, and prolong survival.

Hypothesis: Patterns in diagnostic test utilization and pharmacotherapy among patients with newly diagnosed heart failure may affect outcomes.

Methods: Claims data were analyzed from all diagnostic procedures and prescriptions from 1995 to 1998 in 3,353 patients with heart failure diagnosed within 1 year. Rates of diagnostic testing and categories of drugs prescribed were the main outcome measures. Demographic variables and type of provider were analyzed within a setting whose access to care was controlled.

Results: Rates of diagnostic testing with respect to basic, metabolic/endocrine, alternative diagnoses, underlying ischemia, and left ventricular function varied as a function of gender, age, race, and primary versus specialty care provider. Only 4.7% of patients underwent all diagnostics and treatments recommended in current guidelines. However, those patients (27.5%) who underwent an evaluation for ischemic heart disease and were prescribed vasodilators or beta blockers enjoyed the lowest crude mortality.

Conclusions: There are multiple opportunities apparent to improve the initial diagnostic and therapeutic care of patients with heart failure. There appears to be an early survival benefit with respect to use of vasodilators and beta blockers within the first year of treatment.

Key words: heart failure, diagnostic testing, pharmacotherapy, mortality, primary care, health services research

Introduction

Previous cross-sectional studies from large data sets have shown increases since the 1970s in the point prevalence of congestive heart failure (CHF) in the United States and Europe with age, coronary artery disease, valvular disease, and poorly controlled hypertension as the major determinants.[1–9] However, selection biases for entry into prospective cohort studies and randomized trials have limited generalizability to community care due to a lack of reports on the use of diagnostic testing and pharmacotherapy, as well as underrepresentation of African Americans, women, and the elderly.[10] The purpose of the previously described Resource Utilization Among Congestive Heart Failure (REACH) study was to report on the epidemiology of CHF and its care patterns within an integrated health system.[11] This REACH substudy set out to evaluate the extent of the initial diagnostic evaluation and described patterns of proven pharmacotherapy utilization, with the goal of identifying opportunities for clinical improvement.

Methods

Setting

The methods of the REACH study have been reported previously.[11] Briefly, Henry Ford Hospital is a 903-bed tertiary care center, located in the Detroit metropolitan area, and receives patients whose care is provided primarily within Henry Ford Health System (HFHS), a vertically integrated, mixed-model, managed-care organization (MCO) that includes urban and suburban satellite clinics in Southeast Michigan.[12] Health

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Alliance Plan (HAP), the primary MCO for HFHS, maintains comprehensive administrative tables for encounters within HFHS and hospitals nationwide.

Case Definitions

An index case of CHF was defined as an individual who had accumulated at least two outpatient encounters (emergency department, urgent care, or clinic) or one hospitalization coded for CHF during the study period from 1989 to 2000. This subgroup analysis is restricted to patient-declared index (newly diagnosed) cases between 1995 and 1998. As previously reported in REACH, approximately two-thirds of cases were declared index cases as they were experiencing one hospitalization. The remaining one-third were declared index cases starting with the second CHF outpatient encounter.[11] The 9th International Classification of Diseases, Clinical Modification (ICD-9-CM) codes for CHF used were previously validated in CHF case findings and included the following: 428.XX, 398.91, 402.01, 402.11, 402.91, 404.00, 404.01, 404.03, 404.10, 404.11, 404.13, 404.90, 404.91, 404.93, or hospitalizations with the diagnosis related-group (DRG) 127.[13, 14] Validation of the CHF definition from chart notes has been reported previously.[11] In brief, a random sample of patients in REACH underwent chart review (n = 263, 44.1% women, 55.9% men). Congestive heart failure was confirmed in 82.9% of cases. Most of those who did not have CHF explicitly listed in the chart had the cardiac substrate and associated findings to support the presence of CHF. Only 5.0% had no mention of cardiovascular disease in the chart notes. Death was ascertained in all study patients by death within an HFHS facility, death confirmed by State of Michigan Death Registry tapes, or listed in the National Center for Health Statistics Death Index.

Study Sample

Using the n = 29,686 parent database of patients with CHF, 3,353 patients who belonged to HAP and were continuously enrolled from 1995 to 1998, a period with complete diagnostic test and pharmacy data, were selected for this substudy. Diagnostic tests were considered completed if the test date occurred before the 1-year anniversary of the index date. Drug exposures were taken if at least one prescription for the drug class was filled during the index year. The database was unable to provide more detailed information such as specific drug within class, dose, quantity, or frequency of refills.

Statistical Analysis

Univariate statistics were reported as proportions, or means and comparisons were made with chi-square test or analysis of variance, as appropriate. Multiple logistic regression was carried out to identify the independent relations between demographics, diagnostic testing, and initial pharmacy claims on all-cause mortality. Statistical significance was chosen at the $\alpha < 0.05$ level.

Results

Baseline Characteristics

The mean age was 68.0 ± 13.3 (20.7–103.0) years and 50.5% were women. Racial proportions were as follows: Caucasian 57.4%, African American 39.3%, and other race 3.3%. The other race group was comprised of women and men in the following categories: Hispanic, Native American, Asian, Middle-Eastern, and "unknown or unstated." The types of MCO plans were as follows: Health Maintenance Organization (HMO) alone 56.7%, Medicare HMO 37.8%, and other combined HMO product 5.5%.

Diagnostic Testing

Rates of diagnostic testing are given in Figure 1. Categories of diagnostic testing were grouped by demographics and are given in Figure 2 A–D. The categories formed from the list of recommended tests in the 1994 Agency for Health Care Policy and Research (AHCPR) and the recent American College of Cardiology/American Heart Association (ACC/AHA) guidelines for the evaluation and management of heart failure, were as follows:[15, 16] (1) Basic evaluation included an electrocardiogram (ECG) and chest x-ray; (2) metabolic/endocrine evaluation included thyroid-stimulating hormone (TSH) and biochemistry profile; (3) alternative diagnosis evaluation included a complete blood count and urinalysis; (4) ischemia evaluation included any form of stress testing or catheterization; and (5) left ventricular function evaluation included echocardiography, or left ventriculography by catheterization, or nuclear angiocardiography. Of all cases, 44% were cardiologist managed (defined as two or more visits within 1 year), with a mean age of 66.6 ± 12.8, and 55.8% of patients (aged 69.1 ± 13.5 years) were primary care physician (PCP) managed. Results of echocardiography were available in 599 patients who underwent the examination within HFHS, with a mean ejection fraction (EF) of 46.0 ± 14.9%, range 6–74%. Of note, if an EF of 45%

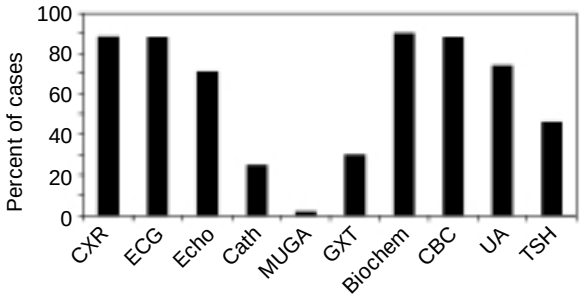

FIG. 1 Rates of diagnostic testing performed in the first year after diagnosis of congestive heart failure in 3,353 Health Management Organization enrollees in the REACH (Resource Utilization Among Congestive Heart Failure) study. CXR = chest x-ray, ECG = 12-lead electrocardiogram, echo = echocardiography, cath = cardiac catheterization, MUGA = nuclear angiocardiography, GXT = graded exercise tolerance test, Biochem = biochemistry panel, CBC = complete blood count, UA = urinalysis, TSH = thyroid stimulating hormone.

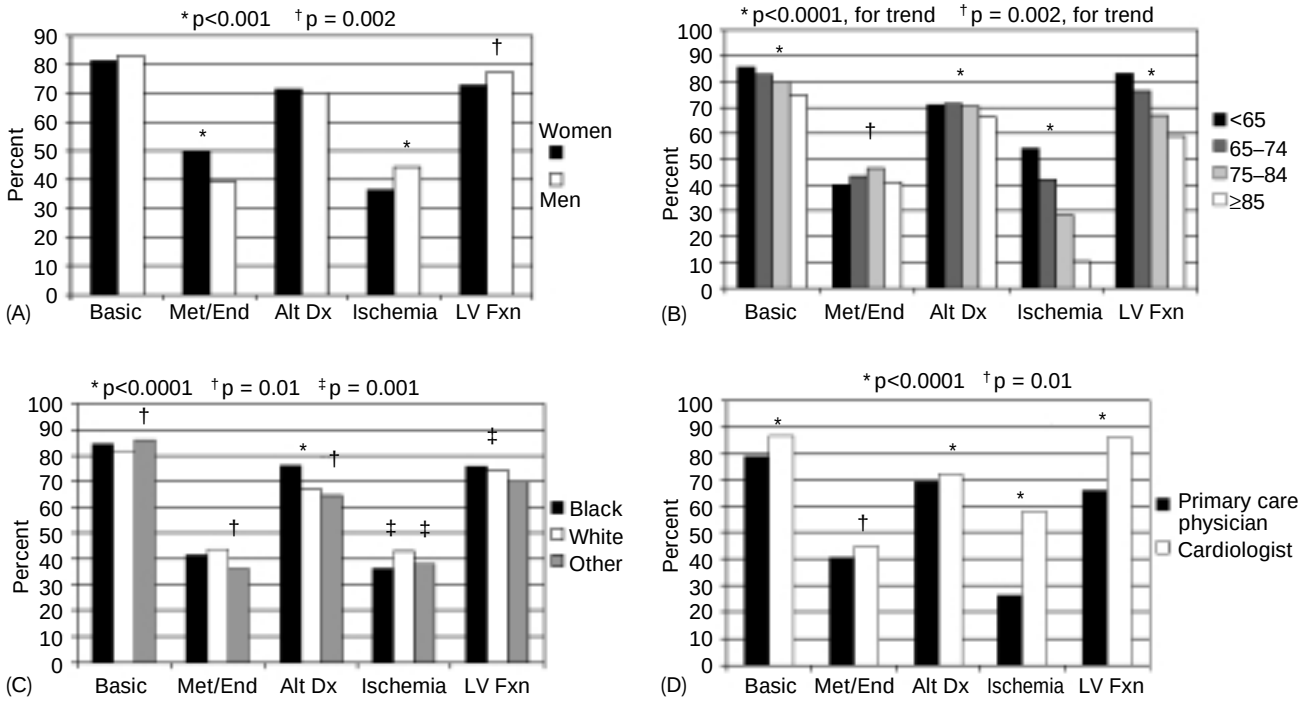

FIG. 2 Rates of diagnostic testing per category according to (A) gender, (B) age, (C) race, and (D) provider type. Diagnostic testing categories are as follows: (1) Basic = basic evaluation included an electrocardiogram (ECG) and chest x-ray; (2) Met/End = metabolic/endocrine evaluation included thyroid stimulating hormone (TSH) and biochemistry profile; (3) Alt = alternative diagnosis evaluation included a complete blood count and urinalysis; (4) Ischemia = ischemia evaluation included any form of stress testing or catheterization; and (5) LV Fxn = left ventricular function evaluation included echocardiography, or left ventriculography by catheterization, or nuclear angiocardiography.

was used to delineate predominately systolic versus diastolic dysfunction, 214 of 599 patients (35.7%) had predominately systolic dysfunction with a mean EF of 28.7 ± 9.4%, and 385 of 599 (64.3%) had predominately diastolic dysfunction with a mean EF of 55.7 ± 6.2%. Patients with predominately systolic dysfunction were only slightly more likely to be cared for by a cardiologist (51.9%) than by a primary care physician (48.1%), p = 0.01. The univariate odds ratio (OR) for the association of an ischemia evaluation and death was 0.67, 95% confidence interval (CI) 0.54–0.83, p < 0.0001. When this association was adjusted for age, gender, and race, the association remained significant (adjusted OR = 0.78, 95% CI, 0.63–0.98, p = 0.03). As a check on lead-time bias, the rates of diagnostic testing were checked by index year for each of the five categories above for the years 1995, 1996, 1997, and 1998: (1) Basic evaluation: 83.8, 82.7, 82.5, and 80.0%, respectively, p = 0.10; (2) metabolic/endocrine evaluation: 40.4, 45.5, 43.1, and 39.5%, respectively, p = 0.50; (3) alternative diagnosis evaluation: 76.2, 74.3, 68.6, and 63.7%, respectively, p < 0.0001; (4) ischemia evaluation: 44.7, 39.5, 39.2, and 39.3%, respectively, p = 0.06; and (5) left ventricular function evaluation: 75.4, 72.8, 75.1, and 77.2%, respectively, p = 0.26 (all p values derived from chi-square for linear trend). This indicated that it was unlikely that cardiac tests prior to 1995, such as catheterization or echocardiography, falsely lowered the rates observed.

Medication Profiling

Rates of medication utilization are given in Figure 3. Medication utilization patterns by demographic groups are given in Figure 4 A–D. Categories of drug utilization are (1) angiotensin-converting enzyme inhibitor (ACEI), (2) beta block-

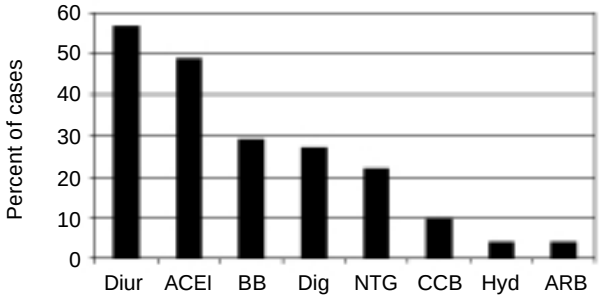

FIG. 3 Overall rates of medication utilization during the first year of heart failure treatment in 3,353 HMO enrollees in the REACH Study. Diur = any form of diuretic, ACEI = angiotensin-converting enzyme inhibitor, BB = beta blocker, Dig = digoxin, NTG = long-acting nitroglycerin, CCB = calcium-channel blocker, Hyd = hydralazine, ARB = angiotensin II receptor blocker. Other abbreviations as in Figure 1.

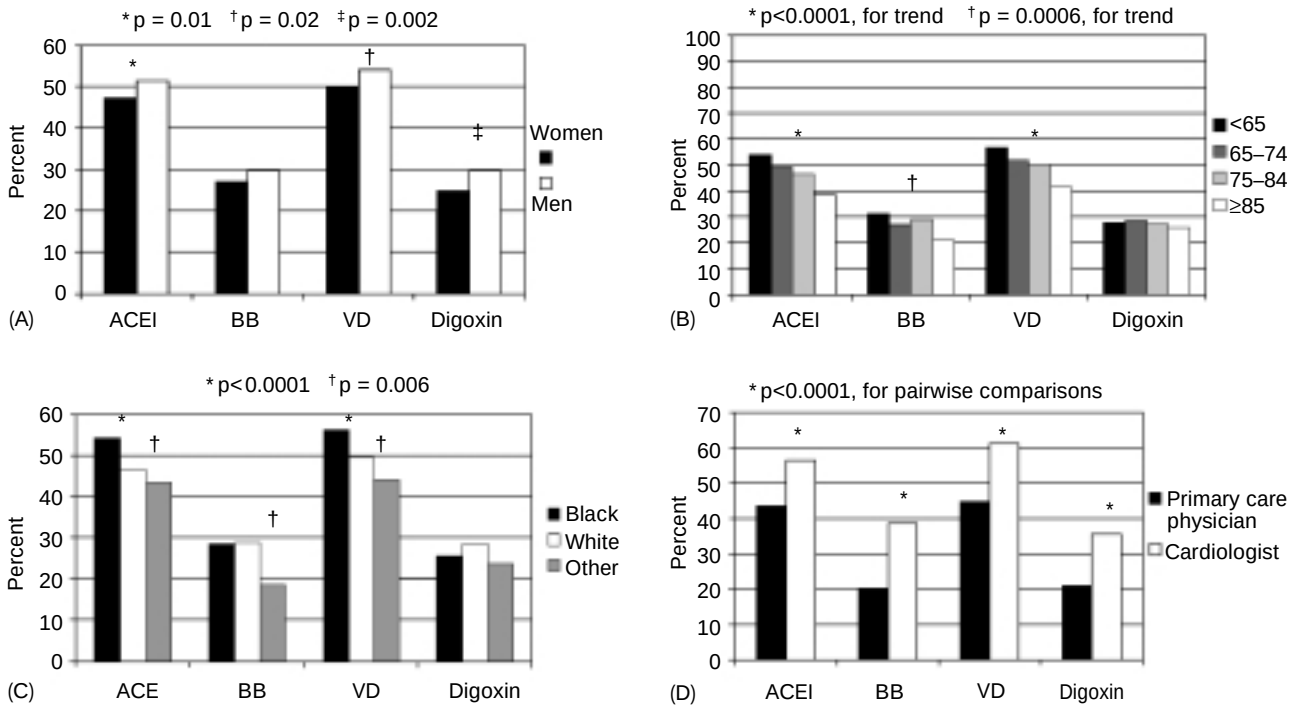

FIG. 4 Rates of medication utilization per category according to (A) gender, (B) age, (C) race, and (D) provider type. ACEI = angiotensin-converting enzyme inhibitor, BB = beta blocker, VD = angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, long-acting nitrates and hydralazine, or a combination of the three.

er (BB), (3) any vasodilator therapy (ACEI, combination of long-acting nitrates and hydralazine, or an angiotensin II receptor blocker [ARB]), and (4) digoxin. In all, 657 patients (19.6%) received both an ACEI and BB. Of note, the data were collected during the time prior to the release of most ARBs on the U.S. market. Figure 5 compares the mortality over the study period of those patients on vasodilator or BB therapy. The database did not specify the primary reason for BB therapy; hence, it was possible for BB therapy to be prescribed primarily for ischemic heart disease in patients who had concomitant CHF.

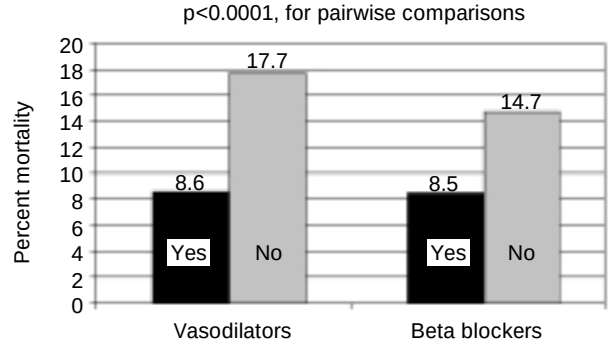

FIG. 5 Mortality rates in 3,353 HMO enrollees by initial medication profile over 20.1 ± 12.7 months. Vasodilators included angiotensin-converting enzyme inhibitors in 1,652/1746 (96.4%), angiotensin II receptor blockers, long-acting nitrates and hydralazine, or a combination of the three.

Initial Package of Care

Only 4.7% of patients underwent complete diagnostic testing and received prescriptions for both vasodilator and BB during the first year of care. A diagnostic evaluation for underlying ischemia was associated with the use of vasodilators and BB (OR = 1.71, 95% CI 1.49–1.97, $p < 0.0001$, and 2.43, 95% CI 2.09–2.83, $p < 0.0001$). Given these relations, we defined a "desirable package of care" to be the performance of an ischemia evaluation and administration of either vasodilator therapy or BB in the first year of diagnosis. Only 27.5% of patients met these criteria; however, there was a significant mortality advantage for those who received this desirable, initial care plan over a mean 20.1 months of observation, (6.7 vs. 15.3%, OR = 0.40, 95% CI 0.30–0.53, $p < 0.0001$). Multivariate analysis confirmed age (OR = 1.024, 95% CI 1.015–1.033, $p < 0.001$), male gender (OR = 1.33, 95% 1.08–1.64, $p = 0.007$), use of vasodilators (OR = 0.52, 95% CI 0.41–0.64, $p < 0.0001$), use of beta blockers (OR = 0.75, 95% CI 0.57–0.98, $p = 0.04$), and cardiologist care (OR = 0.51, 95% CI 0.42–0.67, $p < 0.0001$), as independent predictors of mortality (Hosmer Lomeshow statistic, $p = 0.50$) In this model, which included age at diagnosis, gender, and race, the type of diagnostic evaluation, including whether or not an echocardiogram was performed, was not a significant predictor of mortality.

Discussion

Efforts to implement CHF guidelines and utilize mortality reducing drugs may be impacting the population of patients with CHF in several ways.[15, 16] The methods used in the REACH Study have been shown to be in line with other population estimates of survivorship in CHF, supporting the case that improved treatment of CHF is prolonging the survival of these patients.[17–19] The principal finding of the current study is that there are multiple opportunities to improve the diagnostic evaluation and initial choice of medications for patients with CHF along the lines of the 1994 AHCPR and recent 2001 ACC/AHA guidelines, which were met in full by only 4.7% of our study group.[20–22]

Although the underlying etiologies of CHF in REACH are not known, we would expect, like in other CHF populations, that the leading cause of CHF is ischemic heart disease.[23] The rates we observed, including overall use of stress testing or catheterization (ischemia evaluation) of < 35%, suggest there is a substantial population of patients with ischemic heart disease who may benefit from vasodilator therapy or revascularization.[24] The other message seen in the low stress-testing rate of 30% is that the majority of patients with CHF are not undergoing initial assessment of peak oxygen consumption, a key prognostic variable in selected patients who are considered for transplantation,[25] perhaps indicating that this test is reserved for selected patients, more advanced in their disease state. Analysis by gender and race supported the notion that ischemia is more often sought in men than in women and whites than blacks. The gender bias, which is consistent with other studies, may reflect the fact that men are more likely to have predominately systolic dysfunction (43.9 vs. 27.7% in our echocardiography subset).[26] The racial differences in our study varied as to the type of evaluation, with similar rates for blacks and whites in the basic, metabolic/endocrine, and left ventricular function categories. Alternative diagnoses were sought more in blacks; however, ischemia was more often looked for in whites. These findings are likely due to equal access to care among HAP participants and a relative lack of socioeconomic differences among participants in the study group. Only the elderly were observed to have concordant testing bias by age group in all testing categories; that is, with each successive age group there was less diagnostic testing performed across all categories. The overall low rate of "complete" diagnostic testing was not surprising, given a large (10 or more) number of tests to be performed, the lack of alerts or prompts to clinicians, and the fact that a clinical diagnosis of CHF can be readily made in the absence of many of the tests. It is conceivable that, despite etiology of CHF, reversible disease states such as hypothyroidism could contribute to worsened left ventricular function, hence making relevant the notion of being complete in initial work-up of CHF. We were unable to show that the completeness of diagnostic testing, however, makes a difference in short-term survival. It is clear, though, that those selected to undergo an ischemia evaluation, of whom 39.4% had predominately systolic dysfunction, enjoyed a better short-term survival. Given the lack of revascularization data in our study, this diagnostic testing pattern can serve only as a crude indicator of clinical clues, physician and patient preferences, and the impact of revascularization in a portion who went on to angioplasty or bypass surgery.

Our medication profiling data are consistent with those published by others through the 1990s.[27] Less than optimal use of ACEI and BB has been the rule in outcomes studies despite randomized trials supporting their widespread use.[28, 29] We demonstrated gender differences in that women were less likely to receive ACEI or a vasodilator program; however, women received BB therapy as often as men. We observed a stepwise age bias with older patients being less likely to receive ACEI, BB, or vasodilators. However, all age groups were equally likely to receive digoxin. Perhaps this reflects age bias countered by digoxin use for concomitant atrial fibrillation, which is expected in older groups with heart failure.[30] Of note, usage rates of digoxin, nitrates, and calcium-channel blockers are lower than those in some studies, which may reflect on the high degree of primary care management in REACH. From 1989 to 1997, 76.7% of REACH patients were managed exclusively by primary care physicians who controlled the process of cardiology referral. Our study, gratifyingly, showed that when access to care is equal, blacks are as likely, if not more likely, to receive life-prolonging medications in CHF. This may be due in part to expected higher rates of diabetes and hypertension among blacks not captured in our database. The multivariate analysis clearly showed that efficacious medications predicted from clinical trials have an early independent benefit with respect to all-cause mortality in CHF populations.

In both the diagnostic testing and medication profiling analyses, our data show that cardiologists, on average, have a more complete, evidence-based approach to CHF; however, inferences with respect to processes of care among primary care physicians and specialists are difficult. Prior studies have demonstrated, for example, that cardiologists are more likely to care for patients able to take ACEI on the basis of serum creatinine.[29, 31] There also remains considerable room for improvement with respect to medication profiling among all patient groups. Cardiologist-managed patients in our study still did not reach ceilings of optimal treatment rates with ACEI and BB projected from prior studies.[31] Only 27% of patients were observed to receive a desirable package of care involving an evaluation for ischemic heart disease and to be prescribed either a BB or vasodilator in the first year of CHF. That "desirable package," however, was related to favorable outcomes with a 6.7 versus 15.2% short-term mortality (60.0% risk reduction). It should be pointed out that this "desirable package" is not as well supported in diastolic compared with systolic dysfunction CHF because of a current lack of trial data in diastolic dysfunction CHF. For example, use of ACEI and BB in diastolic dysfunction is a class IIb recommendation in the 2001 ACC/AHA guidelines.[16]

We acknowledge that there are multiple limitations to our study. Using ICD-9-CM codes as the basis for a definition of CHF does not equate to stringent definitions of CHF used in Framingham, the National Health and Nutrition Examination

Survey (NHANES), or other studies, and hence is hampered by misclassification bias.[31] This bias is almost certainly nondifferential and would bias any analytic conclusion to the null hypothesis of testing or treatment comparisons. In addition, these data were collected before U.S. Food and Drug Administration approval of B-type natriuretic peptide as a diagnostic test for heart failure. It is possible that use of this blood test for CHF will markedly enhance the current status of the recommended diagnostic evaluation.[32–34] Use of claims data with respect to diagnostic testing and pharmaceutical usage is a proxy for the real medical transactions that occur in clinics and hospitals. For instance, we had no way of determining the exact temporal overlap of medication classes at any exact point in time. It is important that we acknowledge a temporal time lag between the time of completion of trials, especially BB and ARB trials, and the sampling period, resulting in lower rates of usage than we would expect today. We had no method for assessing for clinical decision-making on the results of diagnostic tests (such as revascularization) or for medication intolerance or noncompliance. In addition, we had no important medical comorbidity data, such as chronic renal disease, which has been shown to influence short- and long-term survival.[35] We believe, however, that our findings can be helpful in understanding aspects of CHF populations and patterns of management, but cannot be generalized to the individual and his or her physician's treatment plan.

Conclusions

We conclude that by use of ICD-9-CM codes and automated sources of data, there are multiple opportunities for improvement with respect to the initial diagnosis and management of CHF. Those patients selected for an evaluation of underlying ischemic heart disease appeared to have a better short-term survival. Although underutilized, early introduction of ACEI and BB appear to be a proxy for high-quality care and improved outcomes. Thus, a suggested "desirable package" of initial care would integrate aspects of the AHCPR 1994 and ACC/AHA 2001 guidelines with respect to ascertaining the etiology (at least to the level of ischemic vs. nonischemic cardiomyopathy), and include recommended treatment to slow disease progression and promote clinical stability including (1) ACEI, ARB, or for those intolerant to both, long-acting nitrates plus hydralazine; and (2) BB within the first year of CHF.[21,36]

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Images in Cardiology: Massive Epicardial Adipose Tissue Indicating Severe Visceral Obesity

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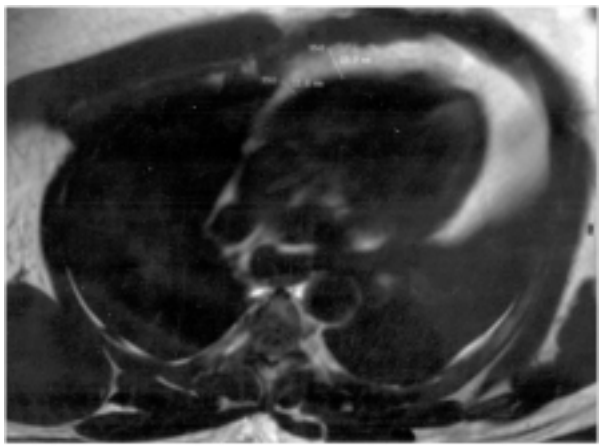

FIG. 1 MRI in a patient with visceral obesity. TSET1-weighted sequence with oblique axial orientation for a correct study of the four cardiac chambers, 10 mm thickness section with 1 mm intersection gap, 370 FOV, 256 ×256 matrix.

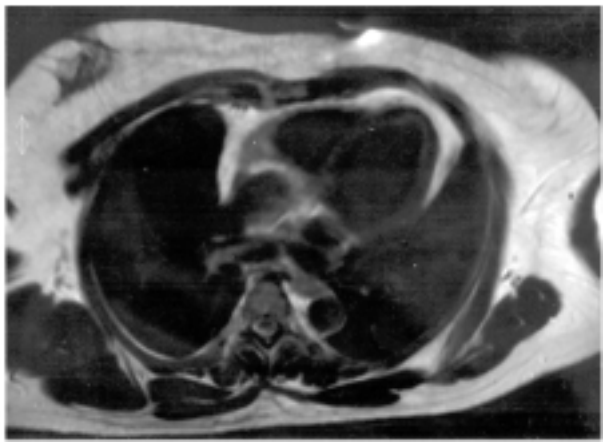

FIG. 2 MRI in a patient with peripheral obesity.

Magnetic resonance imaging (MRI) study of body fat distribution was performed in two obese men of the same age, body mass index (BMI), and duration of excess fat. The first patient had hypertension, diabetes, and high lipids levels. Physical examination revealed a severe visceral obesity with a large truncal-abdominal fat deposition. MRI showed a large abdominal visceral adipose tissue and epicardial fat thickness of 19.9 mm on the right ventricular (RV) free wall and 27.2 mm around the left ventricular (LV) apex (Fig. 1). The second patient presented a peripheral obesity, with prevalent subcutaneous fat deposition but no cardiovascular or metabolic complications. MRI showed epicardial fat thickness of 4.7 mm on the RV free wall and 7.8 mm around the LV apex (Fig. 2). Epicardial fat, a true visceral adipose tissue deposited around the heart, should be considered an important indicator of visceral obesity and high cardiovascular risk independent of BMI.

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