Symptomatic Improvement and Reduced Hospitalization for Patients Attending a Cardiomyopathy Clinic

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Summary

Background: The major costs associated with the management of congestive heart failure (CHF) are inpatient costs. Outcome studies are therefore important to establish whether intensive outpatient care for heart failure can reduce these costs while at the same time improving outcomes in this disabling disorder.

Hypothesis: Care delivered in a cardiomyopathy clinic might result in objective improvement in cardiac function and symptoms while reducing hospital admissions and emergency department visits.

Methods: The outcomes of 21 patients treated for 6 months in a cardiomyopathy clinic are evaluated. New patients referred to the clinic with ejection fraction (EF) <0.45 were enrolled. The Minnesota Living with Heart Failure questionnaire was completed at initial and final visits. All patients underwent baseline and final echocardiogram, radionuclide left ventriculogram, and cardiopulmonary exercise testing. Patients were followed by a nurse practitioner and a cardiologist with maximization of standard treatment. Congestive heart failure-related hospitalizations and clinic and emergency room visits for both 6-month periods before and during the study were determined.

Results: There was significant ($p < 0.05$) improvement in these parameters: Heart failure score increased 23 points; New

York Heart Association class decreased from 2.6 to 2.2; EF increased from 0.24 to 0.36; diastolic and systolic left ventricular dimensions decreased from 65 to 59 mm and from 57 to 50 mm, respectively. The number of clinic visits increased 5-fold, whereas there were 86% (14 to 2, $p = 0.017$) and 100% (8 to 0, $p = 0.002$) reductions in the number of CHF hospitalizations and emergency visits. There was one death during follow-up.

Conclusion: Managing patients in a cardiomyopathy clinic may result in a better quality of life, with both symptomatic improvement and decreased hospitalizations.

Key words: congestive heart failure, echocardiography, outpatient management

Introduction

Despite, or perhaps because of significant reductions in coronary artery disease mortality, the syndrome of congestive heart failure (CHF) secondary to left ventricular systolic dysfunction continues to increase in prevalence.¹ Affecting over 3 million in the United States, it is the most common reason for admission for those over age 65, and estimates of combined costs for inpatient and outpatient care have ranged from 10 to 38 billion dollars per year.^{2,3} Recent estimates place the annual mortality for CHF at approximately 200,000.²

It is not surprising that CHF has been the object of intense research over the past decade. This effort has clearly demonstrated the usefulness of angiotensin-converting enzyme inhibitors (ACEIs) in reducing both symptoms and mortality associated with CHF.^{4,5} Withdrawal of digoxin may worsen symptoms in some patients with CHF and has recently been shown to have no effect on mortality.^{6,7} On the other hand, initially promising agents such as oral milrinone and flosequinan increase mortality and are no longer used.^{8,9} This hard-fought knowledge is not always put into practice; indeed, $<50\%$ of eligible patients receive therapy with ACEIs.¹⁰

The large number of patients with CHF, combined with the observation that optimal therapies are not always offered to these patients, has engendered a debate over how best to provide care for these patients. Traditionally, patients with CHF

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have been cared for individually by internists, family practitioners, and cardiologists. On the other hand, CHF is a complicated syndrome that often requires complex decisions concerning multiple medications, revascularization, valve replacement, and transplantation. A recent study in unstable angina demonstrated that specialists provide better care in some instances.¹¹ If cardiologists and/or heart failure specialists are to have a role in managing patients with CHF, they must show that their care results in better outcomes for the patient. In addition, if costs can be controlled, or better, reduced, this will serve as a further inducement to shift care to specialists in heart failure clinics.

With this background we undertook the present study to evaluate the outcomes of patients with moderate heart failure [i.e., New York Heart Association (NYHA) classes II and III] entering a cardiomyopathy clinic for treatment of CHF. We specifically wanted to answer two questions: (1) in what ways do patients benefit from such a clinic, and (2) can emergency room visits and hospitalizations be reduced? This second question is quite important because substantial reductions in these expensive interventions could conceivably more than make up for funding such clinics.

Methods

The study protocol was approved by the Human Studies and the Research and Development Committees of the hospital's Institutional Review Board.

New patients referred to the Cardiomyopathy Clinic at the Jerry L. Pettis VA Medical Center in Loma Linda, California, were consecutively evaluated for inclusion in the study. In general, patients were referred who had symptomatic CHF despite treatment with digoxin, diuretics, and ACEIs. A nurse practitioner (SAF) screened the patients to determine eligibility for the study. Inclusion criteria were symptomatic CHF with an ejection fraction (EF) ≤ 0.45 , age > 18 years, desire to participate in the study, and willingness to comply with the study protocol. Patients were excluded for the following reasons: age > 80 ; known severe valvular heart disease, forced expiratory volume over the first second of expiration < 1.3 l, primary pulmonary hypertension, any noncardiac condition that would significantly impair exercise performance or life expectancy, and distance from the clinic that would make regular follow-up difficult. Those patients who met the inclusion criteria were provided written informed consent and scheduled for an initial visit.

Once patients had enrolled in the study, they performed a metabolic treadmill exercise test and underwent an echocardiogram and a radionuclide EF determination prior to their first clinic visit. On the day of their initial clinic evaluation, their history was taken and they underwent physical examination and routine laboratory testing, including a complete blood count, serum chemistries, digoxin-level, and thyroid-stimulating hormone determination. The patients also completed a Minnesota Living with Heart Failure questionnaire to assess quality of life.

The follow-up visits were with either a physician or nurse practitioner. The following guidelines were followed for the management of heart failure:

1. We sought to identify the etiologic factors for the CHF using the history and further testing such as angiography when indicated. Myocardial biopsies were not performed. We strongly encourage patients with significant ethanol intake to stop drinking.
2. Surgical intervention was offered to patients when ischemia was thought to play a significant role in the CHF as demonstrated by positron emission tomography or dobutamine echocardiography.
3. We prescribed digoxin for all patients, and the dose was adjusted to maintain a serum level of 1 ng/ml.
4. We employed diuretics to eliminate peripheral edema and to reduce the jugular venous pressure to 7 cm of water and produce a negative abdominojugular reflux test. The goal was the normalization of the jugular venous pressure without more than a 20–30% rise in serum creatinine. The evaluation of the neck veins by means of the physical examination has been shown to be the most sensitive indicator for elevated wedge pressure.^{12, 13}
5. We started and/or titrated all patients on an ACEI (quinapril) with a target dosage of 20 mg twice a day. A systolic blood pressure of 80–90 mmHg was accepted if the patient was not symptomatic at this blood pressure. If patients were intolerant of the ACEI, we switched to hydralazine/isosorbide or an angiotensin-II blocker (losartan) if this was better tolerated.
6. We treated hypertension with high-dose ACEI and the addition of either amlodipine, felodipine, or hydralazine.
7. We offered a trial of empiric beta blockade to patients, using a starting dose of 6.25 mg twice daily of metoprolol with weekly doubling of the dose to a target of 50 mg b.i.d.

The frequency of clinic visits was determined by the severity of CHF and the need for medication titration. We also allocated time to educate the patients about CHF, required dietary restrictions, and pointed out the importance of compliance with their medical regimens. The patients were asked to weigh themselves daily, and we taught them to adjust their diuretics based upon their daily weight. A nurse practitioner was available by telephone to answer any concerns. Patients could be seen during the day without an appointment if they had an exacerbation of CHF or ran out of medications.

After 6 months of clinic follow-up, we again administered the the Minnesota Living with Heart Failure questionnaire along with the echocardiogram, radionuclide ventriculogram, a metabolic exercise test, and routine laboratory tests as described above. In addition, we reviewed the chart of each patient to determine the number of CHF-related clinic and emergency room visits, and hospital admissions during both the study period and the 6 months before enrollment. All studies

were performed and interrupted blindly in order to avoid bias in the study.

The data were analyzed using an SPSS software package (SPSS, Inc., Chicago, Ill.) to determine the statistical significance of any differences in the measured parameters during the study periods. Methods included the paired *t*-test and the chi-square test.

Results

We screened 34 patients during the enrollment period that lasted from July 14, 1994, to July 13, 1995. Although 26 patients met the entry criteria, only 21 agreed to participate. One of the patients died from an acute myocardial infarction during follow-up; thus, only 20 patients completed the study. During the study one patient underwent coronary artery bypass graft and another had this procedure along with mitral valve replacement.

All 20 patients completing the study were men, and 90% were Caucasian. Their mean age at enrollment was 61 (range 45–77) years, with an average duration of symptoms of 22 months.

Coronary disease was the cause of CHF in 60% of patients, 45% had a prior myocardial infarction, 40% had a history of hypertension, 25% had a history of diabetes mellitus, 20% had pulmonary disease, 25% had atrial fibrillation, 25% had prior cardiovascular surgery, and 30% drank alcoholic beverages.

During the study period, the use and dosages of most of the pharmacologic agents increased, as indicated in Figure 1. At the initial visit, 95% of the subjects were using ACEIs, but only 35% were taking a high dose. In addition to furosemide, hydrochlorothiazide use increased from 10 to 20%. By the end of the study period, 10% were receiving amlodipine in addition to ACEIs. At their initial visit, 40% were taking aspirin, 20% were taking warfarin, and these percentages did not change. The use of beta blockers and lipid-lowering agents also tended to increase by 15 to 35% and by 10 to 45%, respectively. At the initial visit, 40% of the patients were taking nitrates.

FIG. 1 Change in quinapril, furosemide, and digoxin doses at entry into the heart failure clinic (baseline) and after 6 months (after clinic).

Clinical and Laboratory Data

The patients' NYHA class improved significantly from 2.6 ± 0.5 to 2.2 ± 0.5 , $p = 0.015$, as did their Minnesota Living with Heart Failure score ($p = 0.001$, Fig. 2). No changes occurred in blood pressure, heart rate, or weight. Exercise time increased from 6.7 to 8.8 min ($p = 0.005$), although the maximum oxygen consumption remained unchanged ($15.4 \text{ ml O}_2/\text{kg}/\text{min}$ initially and $15.3 \text{ ml O}_2/\text{kg}/\text{min}$ at the end of 6 months in the clinic). No significant change was found in serum sodium, blood urea nitrogen, creatinine, or digoxin levels.

Overall improvement occurred in EF and certain echocardiographic parameters during the study (Fig. 3, Table I). No significant change was noted in tricuspid regurgitation velocity, A- and E-wave velocities, E to A ratio, or E-wave deceleration time.

Clinic Visits, Emergency Department Visits, and Hospital Admissions

In general, patients were seen much more frequently as outpatients during the 6 months in the heart failure clinic than during the period before enrolling in the clinic; emergency department visits and hospitalizations decreased by >80% during this time (Fig. 4). Patients were encouraged to visit the clinic, rather than the emergency department, whenever possible during episodes of clinical decompensation.

Discussion

In 1991, nearly three million nonfederal hospital discharges listed heart failure as a primary or secondary discharge diagnosis.² During a time when health care costs must be contained, strategies to reduce the billions of dollars spent in the management of heart failure must be given priority. At the same time, the physician's duty is to ensure that less expensive care does not mean suboptimal care. Is it possible to provide more efficient care that improves outcomes while reducing cost?

FIG. 2 Changes in quality of life at entry into the heart failure clinic (baseline) and after 6 months (after clinic) as measured by the Minnesota Living with Heart Failure Questionnaire. Lower scores indicate improved quality of life as measured by this tool.

FIG. 3 Changes in radionuclide ejection fraction before (baseline) and after treatment (after clinic).

Clinical Improvement

Patients enrolled in this study showed significant clinical improvement during the time of their participation in the study. However, because of the number of changes made in the therapy for these patients, it is not possible to pinpoint which intervention or combination of interventions (e.g., intensification of diuretic therapy, increased ACEI dosage, the addition of beta blockers, or more frequent clinic follow-up) is responsible for this improvement. Most likely this represents a synergistic effect of the optimization of all interventions.

Quality of life as measured by the Minnesota Living with Heart Failure Questionnaire increased by an average of 23 points. This contrasts with the findings of the Veterans Administration Cooperative Heart Failure Trial (V-HeFT) II study, in which there was no improvement in the groups treated either with enalapril or with hydralazine-isosorbide dinitrate.¹⁴ However, with the addition of enalapril, significant improvement in selected components in quality-of-life-questionnaire scores was seen in the Study of Left Ventricular Dysfunction (SOLVD) trial, and improvement has been reported with other ACEIs as well.^{15, 16}

Improved exercise tolerance is frequently a goal of therapy for CHF. Diuretics, ACEIs, and beta blockers have all been shown to improve exercise tolerance.¹⁷⁻¹⁹ However, the 2-min increase reported here is unusually large. This degree of improvement was not accompanied by a concomitant rise in maximum oxygen consumption, indicating that patients were able to exercise more efficiently. It is likely that they remained deconditioned and might benefit further from formal cardiac rehabilitation.

The clinical improvement seen in this group was mirrored by the amelioration of left ventricular systolic dysfunction. Left ventricular dilation is a hallmark of ventricular dysfunction and a powerful predictor of mortality.^{20, 21} Significant de-

TABLE I Results of echocardiograms at baseline and after 6 months of attendance at the cardiomyopathy clinic

Parameter	Baseline	End of clinic
LVEDD (mm)	65 ± 10	59 ± 11 ^a
LVESD (mm)	57 ± 10	50 ± 12 ^a
FS (%)	11 ± 6	13 ± 8
Degree MR (1-4+)	2.3 ± 1.1	1.0 ± 1.1 ^b
Degree TR (1-4+)	2.2 ± 1.3	1.0 ± 1.3 ^c
TR velocity (m/s)	2.5 ± 0.6	2.6 ± 1.3
E-wave velocity (cm/s)	81 ± 15	77 ± 29
A-wave velocity (cm/s)	74 ± 21	71 ± 30
E/A	1.1 ± 0.6	1.1 ± 2.1

^ap < 0.05.

^bp < 0.001.

^cp < 0.01.

Abbreviations: LVEDD = left-ventricular end diastolic diameter, LVESD = left-ventricular end systolic diameter, FS = fractional shortening, MR = mitral regurgitation, TR = tricuspid regurgitation.

creases in both diastolic and systolic diameters were accompanied by a decrease in the severity of mitral regurgitation. Mitral insufficiency in chronic CHF is detrimental because it increases the load on the failing heart and reduces forward output. Stevenson reported reduction in mitral regurgitation after aggressive reduction of afterload and preload.^{22, 23} Increased pulmonary artery pressures resulting from mitral insufficiency increase right ventricular afterload and impair right ventricular function.²⁴ Right ventricular function is a powerful predictor of exercise tolerance in CHF.²⁵

Ejection fraction of the patients rose during the 6-month study period. The average increase of 12 points is larger than that reported by other studies that evaluated a single interven-

FIG. 4 Total number of hospitalizations and emergency department visits for the entire group for the 6 months prior to enrollment into the clinic and for the 6 months of clinic attendance. Average number of outpatient visits *per patient* for the 6 months prior to entry into the heart failure clinic compared with the period while patients were attending the clinic.

tion. For example, digoxin, ACEIs, and beta blockers have been shown to improve EF, but to a lesser degree than the improvement seen in this study.^{26,27} An increase in EF in V-HeFT I by > 10 points at 6 months was associated with a yearly mortality of 2%; and in V-HeFT II, the group with a similar increase at 13 weeks had an annual mortality of 1%.²² The increase in EF here reflects the fact that multiple interventions, including revascularization, occurred, in comparison with most trials, in which only one intervention is studied.

Reduced Hospitalizations and Emergency Room Visits

The number of hospitalizations and emergency department visits for CHF decreased significantly during the period of clinic participation in our study. Again, digoxin, ACEIs, and beta blockers all have reduced hospital admissions for heart failure.^{5,7,28} Cintron *et al.* reported that frequent visits to a special heart failure clinic resulted in a 60% reduction of hospitalizations.²⁹ Rich *et al.*, in a randomized controlled trial, found that enrollment in a multidisciplinary heart failure program post hospitalization decreased readmissions by 56%.³⁰

Limitations

Our study has several limitations. First, the number of patients enrolled was small; second, they all were men; third, a concurrent control group would have given us a more accurate assessment of the effect of the heart failure clinic on the patients' outcomes. However, it is difficult to ask newly referred patients to delay attendance of the clinic so that they can serve as a true control group. In addition, the study period was rather short and initial gains may not persist over time. The study was unblinded; however, to reduce bias, the exercise studies and the radionuclide EFs were performed by physicians not involved in the study.

Conclusion

Patients with NYHA classes II and III heart failure, referred to a subspecialty heart failure clinic, showed significant improvement in quality of life, exercise duration, ejection fraction and degree of mitral regurgitation, while at the same time demonstrating a substantial reduction in emergency room visits and hospital admissions. These improvements were generally greater than those reported in large clinical trials and probably were due to the optimization and addition of several therapeutic modalities simultaneously. Heart failure clinics may be especially useful in the management of this costly syndrome because they can attack heart failure on several "fronts" concurrently, resulting in synergistic improvement in cardiac function and patient outcome. Although these improvements in outcome must be confirmed in larger, perhaps randomized trials, this study offers the prospect of an optimistic scenario in the management of heart failure in which significant patient improvement is accomplished at lower overall cost because of reduction in hospitalizations.

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