The Benefit of Implementing a Heart Failure Disease Management Program

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Background: To handle the increasing complexity of congestive heart failure (CHF) care, several new models for the care of patients with CHF have been developed to replace traditional strategies. We undertook this study to evaluate the potential benefit of implementing a CHF disease management program at a tertiary care center, particularly in terms of β-blocker use and cost to the health care system.

Methods: After reviewing the literature regarding therapies and management strategies for patients with CHF, we developed the Duke Heart Failure Program. All enrolled patients had 1 of the following: recent CHF hospitalization, ejection fraction less than 20%, or symptoms consistent with New York Heart Association class III or IV. We compared preenrollment and postenrollment medication use and resource utilization.

Results: We enrolled 117 patients from July 1998 to April 1999. Mean enrollment time was 4.7 months. β-Blocker use and dose significantly increased (52% vs 76% for β-blocker, \(P<.01\); 6% vs 13% of target dose, \(P<.01\)). The hospitalization rate decreased (1.5 vs 0 hospitalizations per patient-year, \(P<.01\)), while the number of clinic visits increased (4.3 vs 9.8 clinic visits per patient-year, \(P<.01\)). The Duke University Health System saved a median of $8371 per patient-year.

Conclusions: Implementing a CHF disease management program was associated with improved CHF medication dosing and with decreased hospitalization for patients with CHF. A CHF disease management program is an effective method for a health care system to care for patients with CHF.
METHODS

The Duke Heart Failure Program (DHFP) was designed by incorporating specific concepts from previously described disease management programs that matched the needs of the Duke University Health System.2–4,7,8,11–13 Protocols were developed for management of medications, including angiotensin-converting enzyme (ACE) inhibitors, β-blockers, digoxin, diuretics, alternative therapies for ACE inhibitor–intolerant patients, including angiotensin-receptor blockers or hydralazine hydrochloride–nitrates, lipid-lowering agents, and other strategies targeted at optimizing the control of concomitant illnesses that may worsen the CHF state, such as hypertension and ischemic heart disease. In addition, the CHF team designed protocols for exacerbations, including shortness of breath, chest pain, and weight gain. The group developed a patient education manual that reviewed topics such as the purpose of each medication, the importance of adherence, potential adverse effects and appropriate actions to take should adverse effects occur, low-salt and low-cholesterol diet, weight monitoring, physical activity, and resources available to patients with CHF. The manual included a daily diary for weights and diet. An inpatient consultation and an outpatient CHF clinic were initiated. Unlike other studies or programs, cardiopulmonary exercise testing or hemodynamic monitoring were not routinely performed.

Based on these protocols and the severity of the patient’s illness, a follow-up schedule for clinic visits and telephone calls would be initiated at the time of enrollment. The basic schedule for patients with New York Heart Association (NYHA) class IV disease included weekly clinic visits for the first month and weekly telephone calls for the first 3 months. The frequency of clinic visits and telephone calls could be modified by the physician. The clinic schedule for NYHA class II and III patients was every 6 weeks with biweekly telephone calls. This schedule would be updated based on changes in medications and symptoms to provide a set number of follow-up contacts for patients. During each clinic visit and telephone call, the nurse practitioner or nurse specialist reviewed with the patient any changes in weight using the weight diary from the education manual. There was no home-monitoring system used as part of the program. All weights and vital signs, if taken by the patient, were self-reported. The DHFP physicians approved all protocols, schedules, and patient material.

Before enrollment began, primary care physician practices in the Duke University Health System were presented an outline of the program, including enrollment criteria. We presented the DHFP to the internal medicine house staff and attending physicians. Pocket cards with inclusion criteria and referral telephone numbers were provided to house staff and placed at all internal medicine nursing stations at Duke University Hospital.

Enrollment in the CHF program began July 5, 1998. At the time of enrollment, patients underwent an initial evaluation. A medical history was obtained with a focus on etiology of left ventricular dysfunction. The DHFP pharmacist reviewed medications with patients and provided an evaluation of medications for the DHFP physician. The nurse practitioner and pharmacist reviewed educational material with the patients, with an emphasis on weight monitoring and a proper procedure for contacting a DHFP nurse practitioner if symptoms worsened. Once the DHFP physician had evaluated the patient and reviewed the data collected by the CHF program team, the attending physician and the DHFP team initiated a plan for any further diagnostic evaluation, medication titration, and follow-up. The plan followed the prespecified protocols and schedule developed for the program.

The DHFP team determined patient eligibility for the program at the end of the initial evaluation based on the

RESULTS

One hundred seventeen patients were enrolled between July 5, 1998, and April 15, 1999. Table 1 shows baseline characteristics at the time of enrollment. The median age of patients was 62 years. Forty-seven percent of the patients lived more than 48 km from Duke University Medical Center. The median ejection fraction was 23%; 50% had symptoms consistent with NYHA class III or IV. A cardiologist participated in the majority of patients’ care prior to enrollment. Twelve patients died while enrolled in the program. The median follow-up was 4.9 months.

The use of ACE inhibitors was high in referred patients and did not change significantly once patients were enrolled in the program (preenrollment vs postenrollment, 78% vs 79%; P = .75). Although the median percentage of patients taking an ACE inhibitor or a β-blocker significantly increased from 50%, there was a significant overall increase in the percent target dose (median [25th, 75th percentiles], 50% [8%, 100%] vs 50% [13%, 100%]; P < .01). Both the use and the percent target dose of β-blockers significantly increased from the time of enrollment to the time of analysis (52% vs 76% use, P < .01; percent target dose [25th, 75th percentiles]: 6% [0%, 25%] vs 25% [6%, 50%], P < .01) (Figure 1).

To assess changes in practice pattern within the community, we evaluated the use of ACE inhibitor and β-blocker at the time of enrollment for 3 different periods in the program: early (months 1-3), intermediate (months 4-6), and late (months 7-10) (Table 2). There were no significant differences between periods in the percentage of patients taking an ACE inhibitor or a β-blocker.

There were significant changes in the inpatient and outpatient events (Table 3). There were 146 admissions within 1 year of enrollment, 41 of which occurred within 30 days of enrollment. There were 57 hospitalizations in the enrolled cohort. Hospitalizations significantly decreased from a median of 1.5 hospitalizations per patient-year to 0 (P < .01). The distribution of patients by the number of hospitalizations for the preen-
following criteria. All enrolled patients had 1 of the following: recent CHF hospitalization, ejection fraction less than 20%, or symptoms consistent with NYHA class III or IV. Patients not meeting the enrollment criteria had a detailed clinical note including an assessment and plan sent to the referring physician with a schedule for follow-up in that physician’s clinic.

The inpatient service for the program provided consultation for patients either in the program or identified as potential enrollees. Before discharge, patients would be scheduled for a follow-up clinic appointment to occur within 1 week. They would also be provided with education material and a telephone number to contact the CHF program, if necessary.

The DHFP maintained all clinic notes and telephone follow-up records. Data collection for analysis was performed at 3-month intervals; information on demographics, patient characteristics, referring physicians, and medications (ACE inhibitors and β-blockers only) were obtained from the CHF program records. Data on number of clinic visits, number of hospitalizations, length of stay, and cost within the Duke University Health System were obtained from the hospital administrative database and the physician organization at Duke University Medical Center. The medical center uses a data system that incorporates true cost data, obtained through time-management studies and integrating costs for ancillary services, materials, laboratories, and indirect services. To obtain cost from the physician administrative database, Medicare-allowable charge was used as a surrogate cost. Cost data from both the hospital and physician databases were categorized as inpatient and outpatient costs based on internal definitions. Patient data were obtained for only the 365 days preceding enrollment.

The statistical analysis was done using JMP IN software (SAS Institute, Cary, NC). Medians, 25th percentile, and 75th percentile for continuous baseline characteristics were obtained. Categorical variables are expressed as percentages. We performed comparisons as paired results of patient’s preenrollment vs postenrollment values. Except for length of stay and the cost of each discharge, continuous variables were analyzed using the Wilcoxon signed rank test of the differences. The average length of stay and cost per discharge were compared for only those patients experiencing a hospitalization, and the Wilcoxon rank sum test was used to test for significant differences between preenrollment and postenrollment events. The categorical variables were compared using the Pearson χ² test. Differences between medication dose and percent of target dose for a specific medication were compared between enrollment and the time of analysis, defined as the last recorded dose prior to April 13, 1999. Differences between hospitalizations, clinic visits, and cost were compared between preenrollment time up to 1 year and postenrollment time.

To account for the difference in the time accumulated by the participating patients prior to enrollment and the time for the patient cohort after enrollment, hospitalizations, clinic visits, total cost, inpatient cost, and outpatient cost were multiplied by a constant. The constant was the total number of days accumulated by all the patients during either the period before enrollment or after enrollment, divided by 365 and the number of patients ([1/sum of patient-days in period for all patients in cohort]/365) × 117. Thus, results were reported as hospitalization, clinic visit, or cost per patient per year. The average length of stay and the cost per discharge were not multiplied by the constant.

The institutional review board at Duke University Medical Center reviewed and approved the DHFP prior to enrolling patients. Patients signed consent forms giving permission to publish results without patient identification.
adjustments and limitations to β-blocker therapy such as blood pressure, heart rate, CHF symptoms, and comorbidities such as pulmonary disease.

Although 2 additional referred patients tolerated initiation of an ACE inhibitor, this increase in use was not significant. Patients were unable to tolerate the medication for a number of reasons, including cough, worsening renal function, hyperkalemia, and hypotension. The absence of a significant impact in ACE inhibitor use by the CHF program results from the high use of this drug (77%) at the time of the initial evaluation. Hanumanthu et al found a similar nonsignificant change in ACE inhibitor use when studying the impact of a CHF clinic on CHF management (76% at baseline vs 74% at 6 months; P value not significant). One possible explanation for this lack of effect is that earlier studies showing poor utilization of ACE inhibitors17-21 are outdated and may not reflect current practice patterns. The inability for 20% of patients to tolerate any ACE inhibitor is not dissimilar to the intolerance found in highly selected patients participating in recent clinical trials.22

β-Blockers’ relatively new status as a beneficial medication for patients with CHF may be reflected in a lower use of this medication by physicians.14-16 The lower use of β-blockers at the time of enrollment (52%) provided an opportunity to significantly increase β-blocker use to 76%. Even the 52% rate of β-blocker use at the time of enrollment was higher than expected, based on national trends showing lower use of β-blockers.22 This may reflect that the referrals came from physicians associated with an academic institution where new information is readily available, or an expected improvement in current practice patterns that are not reflected in previous publications.

The improvement in hospitalization confirmed the results of other CHF disease management programs. Fonarow et al and Hanumanthu et al found that CHF clinic...
ics were associated with decreased hospitalizations (429 admissions for the diagnosis of CHF to 63, \( P < .001 \); 219 preenrollment to 116 postenrollment, \( P < .01 \)). Predischarge planning and close follow-up, used by Rich et al,\(^7\) reduced hospitalizations by 13.2% (95% confidence interval, 2.1%-24.3%; \( P = .03 \)). Clinical pharmacist and nurse practitioner case management have also been shown to decrease hospitalization.\(^{10-12}\)

The reduction in hospitalization was likely due to 2 aspects of the program: increased use of proven therapies and close monitoring that included easy access. In SOLVD (Studies of Left Ventricular Dysfunction),\(^22\) patients with CHF who were taking enalapril maleate had a 40% risk reduction (95% confidence interval, 30%-48%) of hospitalization as early as 1 year. \( \beta \)-Blockers have been shown to reduce all-cause hospital admissions.\(^{13,16}\)

Although ACE inhibitor and \( \beta \)-blocker use can improve clinical outcomes as early as 1 year, the median time of program participation was 4.9 months. The improvements seen in hospitalizations and costs were not likely due only to improved medication use. There is precedent for a disease management program improving clinical outcomes in such a short period. Rich et al\(^7\) saw the benefit of their program in 3 months. In that study, there was no significant difference between the intervention group and the control group in the medicine regimen at time of discharge. A characteristic common to all these programs is the close monitoring of patients through telephone contact or clinic visits. Not only did the DHFP incorporate scheduled contacts, but a contact number was provided for patients to use 24 hours a day, 7 days a week. Patients were educated to contact the program’s nurse practitioner if symptoms worsened. The scheduled calls and clinic visits and the emergency contact system allowed the program providers to intervene when patients’ conditions were worsening but before they required hospitalization.

A potential third reason for improving outcomes in a short period is the positive impact of disease management programs on patients’ lifestyles. Active participation in a program may be a surrogate marker for patients’ desire to make positive lifestyle changes such as daily weight measurement, decreasing salt and fluid intake, and improving medication compliance. A major emphasis of the program is patient education, including providing patient manuals with weight and diet diaries.

The decrease in cost for caring for participating patients is an obvious consequence of decreasing hospitalization. Hospitalizations represent not only a significant morbidity to patients with CHF, but also the most significant portion of the cost for caring for this patient group, up to 80%.\(^{24,25}\) Using inpatient data, both Rich et al\(^7\) and Fonarow et al\(^8\) found a decrease in cost for the management of patients with CHF using a disease management program. The DHFP found a median decrease of $8571, driven by the median $6963 decrease in inpatient costs. Outpatient costs increased by $659, due to an increase in clinic visits. The shift from inpatient care to outpatient care was expected, given the emphasis on frequent clinic visits and close monitoring of patients.

We performed the analysis without data from the patients who died while enrolled in the program and found no significant change in the conclusions of this study. We predicted that deaths would have made the results of the study look more favorable for the program. However, the intensity of care provided to patients at their request or their family’s request is associated with high resource utilization. Part of the program’s education manual and an emphasis for the program is to discuss patient wishes in emergencies and development of a living will.

The program did decrease the median length of stay by 1 day (17%) and the median cost per discharge by $3763 (35%). The reason for the greater percent decrease in cost vs the percent decrease in length of stay is unclear. In our practice, we have noted that the improved communication between the outpatient clinic and the inpatient service allows for a decrease in repeating certain tests. In addition, the physicians participating in patient care have come to a consensus regarding the use of procedures such as right-sided heart catheterizations, diagnostic cardiac catheterizations, and revascularization procedures.

The cost of implementing the program was approximately $175000 or $1500 per patient. Expenses included percent time of staff (nurse practitioner, secretary, pharmacist, and nurse specialist), physician time, materials (computer, office supplies, and education manuals), and overhead for office space. We estimated that the nurse practitioner and nurse specialist spent approximately 50% of their time on the program during the study. The pharmacist spent approximately 25% of a week working with program patients. Since other types of professionals (including social workers and dietitians) were used sparingly, we did not include them in our estimate for the expense of the program. A large portion of the cost is fixed or fixed variable, and would not be expected to change until enrollment reached certain threshold numbers. Thus, as more patients are enrolled in a program, the cost of initiating and maintaining a CHF program would not increase as much as the increased cost sav-

<table>
<thead>
<tr>
<th>Resource</th>
<th>Preenrollment Value</th>
<th>Postenrollment Value</th>
<th>Difference (Preenrollment – Postenrollment) Value</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient costs per patient-year</td>
<td>1041 (132, 3231)</td>
<td>1579 (701, 4548)</td>
<td>659 (−730, 2011)</td>
<td>&lt;.01†</td>
</tr>
<tr>
<td>Inpatient costs per patient-year</td>
<td>11 847 (0, 25 975)</td>
<td>0 (0, 7210)</td>
<td>−6963 (−19 588, 0)</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Cost per discharge</td>
<td>10 859 (6053, 15 137)</td>
<td>6896 (4618, 11 253)</td>
<td>−5763 (−2186, 9499)</td>
<td>.02‡</td>
</tr>
<tr>
<td>Total cost per patient-year</td>
<td>16 025 (3289, 31 133)</td>
<td>2544 (750, 12 899)</td>
<td>−8571 (−21 413, 1522)</td>
<td>&lt;.01</td>
</tr>
</tbody>
</table>

*Continuous variables are given as median (25th, 75th percentiles).
†Costs per patient-year are compared using Wilcoxon signed rank test of the differences between preenrollment and postenrollment for each patient.
‡Costs per discharge are compared by Wilcoxon rank sum test; no difference by patient was calculated.
dings one would realize. This has been the case for the DHFP as it has continued to grow.

The most obvious limitation of this study is that there was no randomization of patients to the CHF program vs standard care. The investigators had to use historical data from the patients as a control. There are a number of biases that can occur using this type of analysis. It can be difficult to know if the disease management program caused the improved outcomes. Patients’ conditions may have improved over time, thus explaining the improved outcomes. However, given the natural course of cardiomyopathies, we believe that this is unlikely. Trends within the community practice environment could have caused some of the benefit. Yet, we did not find any significant change in the use of ACE inhibitors or β-blockers at the time of enrollment for participating patients.

Another potential bias is the effect of hospital admissions that identified patients for the program. Since patients admitted for CHF are more likely not to be admitted over the initial postdischarge period, there is a chance that the postenrollment outcome benefited from the expected low readmission rate. This is described as regression to the mean. Although we do not have any specific information regarding where referrals took place, we do know that 41 hospitalizations took place within 30 days of enrollment. In addition, there is no regression to the mean when considering average length of stay or the costs per discharge.

In addition, the study was conducted at a single center; the results may be specific to the Duke University Health System. As with other studies of disease management programs, it is difficult to identify which components of the program played a role in achieving the outcomes. The opportunity to replicate this concept in other practice settings would be more feasible if the critical components could be identified and a simpler program focusing on these elements could be developed.

CONCLUSIONS

This study shows an association between enrollment in the DHFP and improved medication use and decreased cost. The improvement in ACE inhibitor use seen in other studies was extended to β-blocker use in this study. A CHF disease management program is an effective method both in terms of quality of care and cost savings for a health care system to care for patients with CHF.

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REFERENCES