Heart Failure Disease Management Programs  
Not a Class Effect

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Heart failure (HF) remains a major public health problem that affects 5 million patients in the United States. HF is the leading cause of hospitalization for people 65 years of age and older, and rates of hospital readmission within 6 months range from 25% to 50%. The personal burden of HF includes debilitating symptoms, frequent rehospitalizations, and high rates of mortality. HF also poses a substantial economic burden, with annual direct costs for the care of HF patients estimated to be between $20 billion and $56 billion. A number of studies have documented marked variation in the quality of care judged by specific performance measures and substantial underuse of evidence-based, guideline-recommended HF therapies in patients receiving conventional care. Moreover, patient behavioral factors (such as nonadherence to diet and medications) and economic and social factors frequently contribute to rehospitalizations. The traditional model of care delivery is thought to contribute to frequent hospitalizations because in these brief episodic encounters, little attention may be paid to the common modifiable factors that precipitate many hospitalizations. As such, there has been much interest in identifying effective methods to improve the quality of care for HF patients while reducing costs.

We and others first studied the use of comprehensive HF management programs involving specialty care and a multidisciplinary team; the goals of the HF disease management (DM) programs included optimization of drug therapy, intensive patient education, vigilant follow-up with early recognition of problems, and identification and management of patients’ comorbidities. HF patients who were cared for in these programs were shown to have significantly fewer rehospitalizations, lower healthcare costs, improved functional and symptom status, and better quality of life as compared either with their preintervention status or with HF patients being treated with conventional care. Because these initial studies of multidisciplinary DM interventions were nonrandomized “before-and-after” studies, concerns were raised about their interpretation. Rich and colleagues were the first to provide randomized clinical trial evidence for the effectiveness of DM in improving clinical outcomes in HF patients. They developed a nurse-directed, multidisciplinary DM intervention to address risk factors for readmission, including nonadherence to diet or medications, inappropriate prescribing of medications, and failure to recognize HF exacerbations. In their single-center study of high-risk HF patients, they reported a reduction of HF readmissions within 90 days by 56%, all readmissions by 29%, and overall cost of care by $460 per patient.

Other studies of multidisciplinary DM interventions confirmed Rich and colleagues’ findings. McAlister et al reviewed randomized trials of HFDM programs published through 1999 and concluded that multidisciplinary teams providing direct specialized follow-up care statistically significantly reduced hospitalization and healthcare costs, whereas studies that used telephone contact to coordinate primary care services seemed to have no effect. Since 1999, several more randomized trials have been published. In an updated analysis by McAlister and colleagues, HFDM strategies that incorporated follow-up by a specialized multidisciplinary team (either in a clinic or nonclinic setting) reduced mortality (risk ratio [RR] 0.75, 95% confidence interval [CI] 0.59 to 0.96), HF hospitalizations (RR 0.74, 95% CI 0.63 to 0.87), and all-cause hospitalizations (RR 0.81, 95% CI 0.71 to 0.92). In addition, investigators from 15 of the 18 trials reported that the DM interventions that were used reduced costs; researchers from the other 3 trials reported cost neutrality. Strategies that used telephone contact and advised patients to contact their primary care physician in the event of deterioration were found to reduce HF hospitalizations but not mortality or all-cause hospitalizations. Another recent meta-analysis that included 18 trials published between 1993 and 2003 confirmed that, overall, DM interventions directed at recently hospitalized patients with HF significantly reduce rehospitalization and healthcare costs, with a trend toward lower all-cause mortality rates. The authors concluded that if applied on a national basis, multidisciplinary DM strategies for HF have the potential to prevent 84 000 readmissions, with an estimated reduction in Medicare payments of $424 million per year.

In this issue of Circulation, Galbreath et al report on a single-center randomized controlled trial of a DM intervention. A total of 1069 men and women, 18 years of age or older, with symptoms of HF and documented systolic or diastolic dysfunction were enrolled. The DM program was administered telephonically via a commercial vendor that was distinct from each patient’s usual source of medical care. The patients enrolled were a mean age of 71 years old, 29% were...
women, and 70% had systolic dysfunction HF. The DM-intervention patients were shown to have a reduced mortality rate, and the beneficial outcomes were more apparent in patients with systolic HF. Although improvements in NYHA class were more likely with DM, 6-minute-walk data from 217 patients for whom data were available showed no significant benefit from DM. Total and HF-related healthcare consumption, including medications, office or emergency department visits, procedures, or hospitalizations, were not decreased by DM. The authors conclude that although DM is associated with reduced mortality in HF patients, it is unlikely to produce a significant reduction in healthcare costs.17

The authors should be commended for conducting such a large and well-reported trial of DM in community-based outpatients with HF. Several characteristics inherent to the DM program in this study, however, must be considered before generalizing these conclusions. The DM intervention approach used in this program, telephone contact to coordinate education and primary care services, has previously been shown to be less effective than other DM interventions.14–15 There is evidence that the DM program used in the study by Galbreath and associates was not sufficiently effective at implementing evidence-based therapies. Although the DM-intervention patients with systolic dysfunction HF were more likely to be treated with a guideline-recommended therapy at the end of the trial than were the control patients, close to half of the DM-intervention patients were not being treated with both an ACE inhibitor and a β-blocker. Furthermore, tracking of performance measures other than medications and use of continuous cycles of quality improvement was not reported.

The extent of training provided to the commercial disease managers in this study is not well documented. The patient’s treatment was left to the physician’s discretion, and although summary reports were faxed to all physicians’ offices, it appears that no other attempts at communication or coordination of care between the disease manager and the physician occurred unless the patient called a toll-free number.17 Half of the treatment group was given in-home technology, including an electronic blood pressure monitor and finger pulse oximeter. Readings were reported by the patient to the disease managers, but these data were not forwarded to the primary care provider or used in clinical decision-making, nor were the results of other physiological tests being performed reported to patients’ physicians.17 Anyone could question the purpose of collecting such information if it was not being used to improve patient care and whether collecting but not using these data distracted disease managers from focusing on patient care and quality improvement.

Should the findings from this trial be taken to mean a “class effect” exists with regard to DM programs? Should these findings apply to all HFDM programs? As this and other trials illustrate, the content and effectiveness of HFDM interventions vary widely. Substantial differences in program design likely explain differences significant differences in health-related outcomes. The programs reported on to date have differed substantially in intervention focus (eg, patient self-management, medication management, and care coordination), mode (telephone, home, or specialty clinic visit), timing in relation to index hospitalization, intensity (frequency and duration of contacts), disease manager training, the cardiologist’s involvement, and nature and extent of interaction with the patient’s primary care physician.14–16,18 Furthermore, even with a similar focus, different DM programs may differ substantially in their ability to implement change and improve health-related outcomes.

The patient populations to which the HFDM program was applied are also an important consideration.18 The present study included patients with systolic and preserved systolic function HF, but so did a number of other DM studies that demonstrated benefit.10–13 Galbreath and colleagues’ trial did differ from most other studies of DM in that it targeted outpatients rather than those with recent HF hospitalizations. The inclusion of stabilized outpatients without recent hospitalizations who agree to participate in a trial and undergo screening echocardiography appears to have resulted in a lower-risk patient population than in other studies. An 18-month mortality rate of only 11.9% in the usual care group in this trial is significantly lower than that of other DM trials. Limited benefit also was observed in a recent study of patients with HF at low risk on the basis of sociodemographic and medical attributes in a health maintenance organization setting, wherein nursing care management provided structured telephone surveillance and treatment for HF and coordination of patients’ care with primary care physicians.19 Thus, the benefits of specialized DM programs for HF that target patients at higher risk with advanced HF, recent hospitalizations, older adults, and populations that are underserved or vulnerable may not be generalizable to lower-risk HF patients.17-19

To address the complex issues surrounding DM, the American Heart Association (AHA) assembled a multidisciplinary Advisory Working Group on Disease Management to offer ongoing guidance in this evolving area.20 This group recently released a report recommending 9 guiding principles for the development, implementation, and evaluation of DM initiatives, as follows:20

1. The main goal of DM should be to improve the quality of care and patient outcomes.
2. The basis of all DM programs should be scientifically derived, peer-reviewed guidelines. These guidelines should be evidence based and consensus driven.
3. DM programs should help increase adherence to treatment plans based on the best available evidence.
4. DM programs should include consensus-driven performance measures.
5. All DM efforts must include ongoing and scientifically based evaluations, including clinical outcomes.
6. DM programs should exist within an integrated and comprehensive system of care in which the patient–provider relationship is central.
7. DM programs should address the complexities of medical comorbidities to ensure optimal patient outcomes.
8. DM programs should be developed for all populations and should particularly address members of underserved or vulnerable populations.
9. Organizations involved in DM should scrupulously address potential conflicts of interest.
Randomized clinical trials have established that certain DM programs for HF improve prescribing practices and reduce the risk of hospitalization, costs, and mortality; successful programs have included patient education, multidisciplinary teams, and specialized follow-up procedures. In contrast, telephone-based systems designed to enhance follow-up with primary care providers have yielded mixed results and the effectiveness of these programs has not been fully established. Healthcare providers, insurers, and policymakers should now recognize that when it comes to DM programs for HF, no class effect exists. DM programs for HF should strive to adhere to the principles set forth by the AHA and include the elements found to be efficacious in clinical trials—multidisciplinary teams, improved use of evidence-based guideline-recommended therapy, emphasis on patient education and self-management, and enhanced access to specialized clinics or home visits. Although some HFDM programs have been proven to be effective, others have not, and significant additional attention is needed in testing and demonstrating best practices and sharing information about successful program components across a variety of care settings.

References

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