

Evidence-Based Medicine and Population-Based Care: Caring for Patients with Heart Failure

By Anthony Steimle, MD, FACC

Introduction

Heart failure is not only common but—somewhat unique among cardiac conditions—its prevalence is increasing as the population ages and as modern cardiac care allows people with heart disease to survive longer. (I sometimes tell nurses and pharmacists that the prevalence of heart failure adds to their job security.) Despite tremendous advances in therapy, heart failure nonetheless brings with it a heavy burden of both mortality and morbidity. Half of affected patients die within five years after diagnosis, and severe symptoms and hospitalization are frequent.

A fact not widely recognized is that nearly half of patients with heart failure have a normal ejection fraction.¹ Clinical evidence regarding the management of these patients with preserved systolic function is relatively sparse. Fortunately for heart failure patients with a reduced ejection fraction (often called *systolic heart failure*), good evidence does exist regarding disease management. Controlled trials of tens of thousands of patients with systolic heart failure have identified three categories of medication that improve survival.²⁻⁴ These agents—now referred to as *triple therapy*—include beta-blockers, spironolactone, and vasodilators, such as angiotensin-converting enzyme (ACE)

inhibitors. These medications reduce mortality, improve symptoms, and prevent hospitalization—favorable results that provide important impetus for developing clinical programs for management of heart failure.

Within our heart failure program in the Kaiser Permanente Northern California Region (KPNC), the practice of evidence-based medicine must take into account the aspects of cardiac care about which existing clinical evidence is either imperfect or fails to address im-

portant issues. Use of implantable cardioverter defibrillators (ICDs) is one such topic. These devices represent a tremendous advance for patients with severely reduced ejection fraction: ICDs have reduced the risk of sudden death by as much as 90% in these patients, and earlier trials showed^{5,7} that high-risk patients treated with these devices derive a huge benefit from them—as much as a 14% to 20% reduction in absolute mortality over a two-year period. As these devices became smaller and safer to implant, trying them in lower-risk patients made sense; ideally, however, studies of this population should first screen out high-risk patients already known to benefit from the devices.

Recently published studies (MADIT II⁸ and SCD-HeFT⁹) that included both high- and low-risk patients treated with ICDs showed a 4% to 7% absolute reduction in mortality over a two-year period. The question thus arises: If the high-risk pa-

tients had been removed from the analysis, would the residual benefit have been clinically significant? Would this benefit have been cost-effective? We do not know the answer with any certainty, but use of ICDs is nonetheless being expanded to lower risk patients on the basis of this

An important topic lacking sufficient evidence is how to diagnose heart failure.

imperfect evidence.

An important topic lacking sufficient evidence is how to diagnose heart failure. No randomized trial has defined the best approach, and, unfortunately, no single sign, symptom, or test is pathognomonic. Because patients with heart failure can have a normal ejection fraction, normal results of echocardiography do not exclude the diagnosis; and neither does a reduced ejection fraction establish the diagnosis. Yet, because diagnosis is a crucial first step in caring for patients, a portion of our “evidence-based” guideline focuses on diagnosing heart failure despite the lack of sufficient evidence.

Anthony Steimle, MD, FACC, graduated from UCSF School of Medicine and trained in Internal Medicine, Cardiology, and Heart Failure at UCLA. After completing Cardiology training, he remained at UCLA as a Robert Wood Johnson Clinical Scholar. He joined TPMG in 1996 and is director of the Heart Failure Program for KP Northern California. E-mail: anthony.steimle@kp.org.



Putting Evidence into Practice in the KP Northern California Region

Synthesizing the evidence, “warts and all,” into the best possible clinical guideline is a necessary first step—but itself is insufficient—for disease management. Without programs to implement them, guidelines usually have little impact on clinical practice. For this reason, this article describes the KPNC Heart Failure Care Management Program, which is designed to ensure that our members with heart failure receive the best evidence-based care for this condition. Our program often hosts

visitors from other US health plans—and even from other countries—who ask us: What is the secret of the program? Is it our disease management software? Is it our method of training care managers? Is it our medication protocols? Like Archimedes, these visitors seem to be seeking a lever long enough to move the world. *But there is no single*

such lever. In our program, we have learned that we must pull multiple levers to influence clinical practice and that no single approach is equally effective for every clinician or in every clinical setting.

Using Stratified Interventions in Patients with Heart Failure

To identify patients diagnosed with heart failure, KPNC’s heart failure program relies on a registry based on computerized clinical data—a KP forté—and uses interventions stratified by intensity. What most people think of as a heart failure program is active management of the most advanced disease by nurses and pharmacists. This part is the most vis-

ible in the program, but most patients with heart failure actually receive their care both from their primary care provider and from themselves: We educate the patients as well as the physicians. This important part of the program is less visible.

Patient Education is the Best Medicine

Patients with heart failure must take good care of themselves. We know that patients who eat a low-salt diet or who take their medications as directed are much less likely to become hospitalized, but providing this kind of education requires a commitment of time. We use a four-part, eight-hour class to teach self-care skills to patients diagnosed with heart failure. These skills include recognizing decompensation early, medication compliance, a low-salt diet, and—very important—flexible diuretic dosing based on daily fluctuation in the patient’s weight. Patients must realize that a weight gain of 2 lb (.91 kg) in one day or 5 lb (2.27 kg) in one week indicates excessive fluid retention and requires the patient to increase the dosage of furosemide (for example) for a few days. Early elimination of the fluid—ie, before the gut becomes edematous and stops absorbing oral medications—can prevent hospitalization. The classes also discuss exercise, which, a recent meta-analysis suggests, reduces mortality from heart failure by as much as 35%.¹⁰ Overall, independent of any change in medications, a randomized trial has shown¹¹ that this kind of comprehensive education about heart failure reduces rehospitalization for this condition by nearly 40%. Moreover, no single medication prevents hospitalization as effectively. For this outcome, therefore, education truly is the best medicine.

Outreach and Inreach

For outreach, we can use our KPNC registry of 30,000 heart failure patients to generate lists. For instance, we can send clinicians a list of their patients with heart failure who are not receiving ACE inhibitors, and we can simultaneously recommend starting this medication. Unfortunately, the registry lacks detailed clinical information, and our recommendations are not always correct; recommendations are correct for two or three of each ten patients for whom we recommend ACE inhibitors, but the clinician must nonetheless review the recommendations for all ten patients. This task can be frustrating and time-consuming.

I am more enthusiastic about our inreach efforts, which also use the registry data: When a patient who has been diagnosed with heart failure comes for a visit unrelated to heart failure, the computer detects whether the patient is receiving an ACE inhibitor. If not, a reminder suggesting prescription of the medication can be attached to the front of the chart. With the patient and medical record thus made available for the clinician’s immediate observation, less work is required for the clinician to decide whether the recommendation makes sense. The problem with inreach is that many programs use it; the reminder sheets can therefore become cluttered. In addition, each reminder has a certain error rate. I believe that as KP HealthConnect is implemented online (ie, making more detailed clinical information available), our inreach efforts will become much more accurate and effective, and reminders could become more targeted: For instance, when a clinician writing an online progress note reaches the section designed for entry of the assessment and diag-

Without programs to implement them, guidelines usually have little impact on clinical practice.

nostic plan, a reminder to consider prescribing an ACE inhibitor could appear on the screen.

The Heart Failure Care Management Program: Successes and Qualifications

The Heart Failure Care Management Program is designed to address care of the sickest patients—generally those referred from the hospital, from the emergency department, or from their physician. An intake visit takes place with a care manager (nurse or pharmacist), who assesses the patient's needs, reviews the case with a mentor physician, and develops a treatment plan specifying any needed medications to be titrated or diagnostic tests to be administered. Education in self-care skills is begun at this visit, but the patient is nonetheless referred to the heart failure education classes. Follow-up is then done largely by phone; in-person visits for physical assessment are scheduled as needed. At these visits, self-care skills are reinforced, the medications are gradually titrated using detailed medication protocols, and patients are monitored for decompensation. After 3 to 12 months, care of the patient is returned to his or her primary care practitioner if the patient's condition has stabilized. More than 15,000 KP members have participated in the Heart Failure Care Management Program, although only about 4000 of our 30,000 patients with heart failure participate in the program at any one time.

The Heart Failure Care Management Program offers unique advantages. With respect to education, self-care skills are difficult to convey in 15-minute clinic visits but are effectively and efficiently taught in an eight-hour class reinforced by

weekly phone calls from the care manager. Another advantage is the efficiency of medication titration, which can be done easily and effectively by protocol-driven, software-supported disease management but can be tedious and time-consuming for a primary care practitioner. (For instance, beta blockers must be started at a low dose and titrated upward slowly over a two- to three-month period because these drugs can worsen heart failure before improving it.) Another advantage of the program derives from the ability of care managers to track patients in ways that are difficult for primary care practitioners. For instance, the care manager's disease management software supplies reminders when a member has missed a laboratory test. The Heart Failure Care Management Program thus makes titration easier and safer for a medicine such as spironolactone, which necessitates frequent monitoring of the patient's potassium levels.

We are proud of the program; more than 40 nurses, pharmacists, and physicians at 17 different KPNC medical centers have made the program highly effective. Having nurses and pharmacists in the role of care manager has made the program stronger. Each profession brings different but valuable and complementary skills. Another strength has been our semi-annual meetings, where we exchange helpful ideas. Although we have a regional model, each of the 17 KPNC medical centers is free to implement and innovate upon the model as they see fit. One of the more recent innovations has come from Jeffrey Ritterman, MD, and Margery Ginotti, RN, who tried a novel form of music therapy using group drumming. In a randomized trial, these clinicians showed that the drumming substan-

tially decreased depression and increased self-efficacy (J Ritterman, MD, personal communication, October 2004).⁶ This kind of outside-the-box thinking permitted by local innovation is another strength of our program.

Some patients are too ill for protocol-driven care management. These include patients with severe cardiac conditions, such as valve disease, advanced heart failure, or arrhythmia; or patients with comorbid conditions, such as lung disease, psychosocial issues, or renal failure. Each of these patients is unique and requires customized, intensive management. On several occasions, I have been asked to design a "case management" program for these patients; however, I have concluded that the best management for such complex cases is driven not by a protocol or a program but somebody who has gone to medical school—a doctor. The Heart Failure Care Management Program or case management can often provide support in caring for these patients, but this kind of customized care is best when directed and closely monitored by a physician.

Outcomes of the Heart Failure Care Management Program

Although we have not tested our program in a randomized trial, we have monitored our progress via process measures such as appropriate use of ACE inhibitors and beta blockers (which has increased to where nearly all eligible patients are receiving these medications). We have also examined medical utilization among our patients diagnosed with heart failure, and our most recent measurements suggest

I have concluded that the best management for such complex cases is driven not by a protocol or a program but somebody who has gone to medical school—a doctor.

that inpatient medical utilization among these patients is decreasing and has been replaced by outpatient visits—a desired outcome. We also have data showing high member and physician satisfaction. KP members report that the Heart Failure Program improves their care, and the physicians report that they are pleased with the support provided by the program. The most encouraging “bottom line” outcome—mortality rates—have been declining. Mortality from heart failure has been decreased by 15% since the program was implemented. Because we did not conduct a randomized trial, we do not know how much of this decrease in mortality rates would have occurred in the absence of the program; nonetheless, the outcomes suggest that KPNC’s activities are working.

Mortality from heart failure has been decreased by 15% since the program was implemented.

Although cost was part of the impetus for starting the program—we expected to save money by preventing hospitalization—costs for patients with heart failure have remained relatively flat since the program was implemented. However, when we modeled this component, we realized that we should not have been surprised; prolonged survival and increased care—particularly the increased use of pharmaceutical agents—erases most of the cost savings from prevented hospitalization. This finding was reproduced by a recently published randomized trial,¹² in which 1069 patients were randomized to disease management versus usual care. Compared with the group receiving usual care, the disease management group had lower rates of mortality and more improvement of symptoms but not lower costs. I am sure that all clinicians would agree:

Something that prolongs survival, makes our patients feel better, prevents the need for hospitalization, and is relatively cost-neutral can be considered a great bargain. Therefore, this result does not discourage us but instead might be coined in the phrase, “Live to utilize.”

Conclusion

Writing a rigorous clinical guideline is a crucial first step in evidence-based disease management but is insufficient without programs to implement the evidence. For most of our KP members diagnosed with heart failure in Northern California, we combine clinical guidelines with education of clinicians and patients and registry-based outreach and inreach. About 15% of our patients with heart failure receive protocol-driven care from the nurses and pharmacists in our care management program; a smaller, sicker subgroup of patients receive more customized, intensive, physician-directed care. Since implementing this stratified, population-based program, we have observed improved outcomes. Appropriate medication use also has increased, and rates of inpatient utilization and mortality have declined. “Pulling every lever we can find” has allowed us to influence clinical practice and to improve the lives of our members diagnosed with heart failure. ❖

^a Kaiser Permanente of California, Richmond, CA

Acknowledgment

Thank you to Arthur Klatsky, MD, for his help in developing the manuscript.

References

1. Redfield MM, Jacobsen SJ, Burnett JC Jr, Mahoney DW, Bailey KR, Rodeheffer RJ. Burden of systolic and diastolic ventricular dysfunction in the community: appreciating the scope of the heart failure epidemic. *JAMA* 2003 Jan 8;289(2):194–202.
2. Flather MD, Yusuf S, Kober L, et al. Long-term ACE-inhibitor therapy in patients with heart failure or left-ventricular dysfunction: a systematic overview of data from individual patients. ACE-Inhibitor Myocardial Infarction Collaborative Group. *Lancet* 2000 May 6;355(9215):1575–81.
3. Bonet S, Agusti A, Arnau JM, et al. Beta-adrenergic blocking agents in heart failure: benefits of vasodilating and non-vasodilating agents according to patients’ characteristics: a meta-analysis of clinical trials. *Arch Intern Med* 2000 Mar 13;160(5):621–7.
4. Pitt B, Zannad F, Remme WJ, et al. The effect of spironolactone on morbidity and mortality in patients with severe heart failure. Randomized Aldactone Evaluation Study Investigators. *N Engl J Med* 1999 Sep 2;341(10):709–17.
5. Wever EF, Hauer RN, van Capelle FL, et al. Randomized study of implantable defibrillator as first-choice therapy versus conventional strategy in postinfarct sudden death survivors. *Circulation* 1995 Apr 15;91(8):2195–203.
6. Moss AJ, Hall WJ, Cannom DS, et al. Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. Multicenter Automatic Defibrillator Implantation Trial Investigators. *N Engl J Med* 1996 Dec 26;335(26):1933–40.
7. Buxton AE, Lee KL, Fisher JD, Josephson ME, Prystowsky EN, Hafley G. A randomized study of the prevention of sudden death in patients with coronary artery disease. Multicenter Unsustained Tachycardia Trial Investigators. *N Engl J Med* 1999 Dec 16;341(25):1882–90. Erratum in: *N Engl J Med* 2000 Apr 27;342(17):1300.
8. Moss AJ, Zareba W, Hall WJ, et al; Multicenter Automatic Defibrillator Implantation Trial II Investigators. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med* 2002 Mar 21;346(12):877–83. Epub 2002 Mar 19.

9. Bardy GH, Lee KL, Mark DB, et al; Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) Investigators. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N Engl J Med* 2005 Jan 20;352(3):225-37.
10. Piepoli MF, Davos C, Francis DP, Coats AJ; ExTraMATCH Collaborative. Exercise training meta-analysis of trials in patients with chronic heart failure (ExTraMATCH). *BMJ* 2004 Jan 24;328(7433):189. Epub 2004 Jan 16.
11. Krumholz HM, Amatruda J, Smith GL, et al. Randomized trial of an education and support intervention to prevent readmission of patients with heart failure. *J Am Coll Cardiol* 2002 Jan 2;39(1):83-9.
12. Galbreath AD, Krasuski RA, Smith B, et al. Long-term healthcare and cost outcomes of disease management in a large, randomized, community-based population with heart failure. *Circulation* 2004 Dec 7;110(23):3518-26. Epub 2004 Nov 07.
- Available at: www.acc.org/clinical/guidelines/failure/hf_index.htm.
- Kaiser Permanente of California. Care Management Institute. Clinical practice guidelines: heart failure management [monograph on the Intranet]. Oakland (CA) Kaiser Permanente Northern California; 2004 [cited 2005 Feb 7]. Available from: http://cl.kp.org/portal/site/ncal/?epi_menuItemID=b04391a8031635cf8f9e9bd58f07dea0&epi_menuID=700371804081a0691af671918f07dea0.
 - Steimle A. Evidence-based clinical vignettes from the Care Management Institute: heart failure. *Perm J* 2003 Winter;7(1):9-17.

Recommended Reading

- ACC/AHA guidelines for the evaluation and management of chronic heart failure in the adult: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines [monograph on the Internet]. 2001 [cited 2005 Feb 7].

The Art

Memory, prophecy, and fantasy—
the past, the future and the dreaming moment between—
are all in one country, living one immortal day.

To know that is Wisdom.

To use it is the Art.

— Clive Barker, b 1940, writer, artist, and filmmaker