

Treatment of Chronic Heart Failure in a Managed Care Setting

Baseline Results from the Achieving Cardiac Excellence Project

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Abstract

Background: Effective therapy for chronic heart failure (CHF) is underutilized despite a broad consensus regarding treatment recommendations. **Methods:** As a quality improvement project designed to reduce preventable hospitalizations associated with CHF, we examined use of angiotensin converting enzyme inhibitors (ACEI), angiotensin receptor blockers (ARB), and beta-adrenergic receptor blockers (BB) in a population of patients enrolled in a managed care plan. Medicare and commercial enrollees were included. Patients with CHF were identified using claims data (International Classification of Disease 9th Clinical Modification code 428) covering January 1, 1998 through December 31, 1998. Drug utilization data were obtained from the plan's pharmacy benefits database. Data were available for 1220 patients. **Results:** The mean age ($\pm$ SD) was 71 ± 12 years, 53% were female, and 84% were Medicare enrollees. Prescriptions for ACEI, ARB and BB were filled by 52%, 9% and 25% of patients, respectively. Prescriptions for diuretics, digitalis preparations, and calcium channel blockers (CCB) were filled by 69%, 34%, and 32%, respectively. Therefore, almost half of patients with CHF were not receiving ACEI therapy, even though it had been proven to reduce morbidity and mortality related to CHF. Furthermore, three-quarters of patients were not receiving BB therapy, a similarly effective therapy. In contrast, CCB and digitalis have not been convincingly shown to reduce mortality in patients with CHF broadly defined. Utilization of CCB and digitalis exceeded that of BB. **Conclusions:** Managed care organizations should develop, test, and implement network-level strategies designed to optimize the appropriate utilization of effective drug therapies for patients with CHF.

Key Words: angiotensin converting enzyme inhibitors, beta-adrenergic antagonists, heart failure

CHRONIC HEART FAILURE (CHF) is responsible for a large proportion of the demand for health care in the United States and worldwide. Data collected by the American Heart Association indicates that nearly 4,600,000 people are carrying this diagnosis in the United States.¹ The incidence of new cases is roughly 550,000 per year. Nearly 260,000 patients die as a direct or indirect consequence of heart failure each year. The impact of heart failure in the elderly is disproportionately high. The economic impact of heart failure in the United States may be as high as \$40 billion per year, and the problem is growing. Therefore, the efficacy and appropriateness of treatment for chronic heart failure has

become an issue of great public health, economic, and political importance.

The Clinical Practice Guideline released by the federal Agency for Health Care Policy and Research in 1994 remains the foundation for consensus amongst CHF practitioners and is the algorithm employed by most disease management organizations.² Consensus indications for wide use of ACEI in CHF are central to the AHCPR guidelines. Two updates of these guidelines, published by the Heart Failure Society of America and a pharmaceutical industry consortium known as ACTION-HF (Advisory Council To Improve Outcomes Nationwide in Heart Failure) do not contradict the AHCPR

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guidelines but extend them based on evidence more recently obtained regarding use of angiotensin receptor blockers, aldosterone antagonists, and beta-adrenergic antagonists.^{3,4} The 2001 ACC/AHA Guidelines were not published in time to have an impact within the ACE study period.

Effective therapy for CHF appears to be underutilized despite a broad consensus regarding treatment recommendations. Our initial goal in evaluating these data was to determine whether the perceived disparity between treatment recommendations and prescribing habits was reflected by claims data, and to examine age, gender, and Medicare enrollment status-related differences in use of CHF medications.

The Achieving Cardiac Excellence (ACE) Project is a quality improvement program focused on physician education and support of good practice patterns through the use of performance audits with feedback and chart reminders. The stated objectives of the ACE Project are, firstly, to increase appropriate use of angiotensin converting enzyme inhibitor (ACEI) and beta-adrenergic receptor blocker (BB) therapy in patients with CHF enrolled in a network managed care organization and, secondarily, to evaluate the effectiveness of a focused educational project appealing to physicians designed to improve outcomes in CHF management. In this report, we present data on use of medications in the treatment of CHF by primary care providers (i.e., Family Practice, General Practice, Internal Medicine) at baseline, prior to any intervention.

Methods

Subjects. We examined use of angiotensin converting enzyme inhibitors (ACEI), angiotensin receptor blockers (ARB), and beta-adrenergic receptor blockers (BB) in a population of patients enrolled in a network-model managed care plan, QualChoice of North Carolina, Inc. This was the managed care plan of the Wake Forest University School of Medicine and North Carolina Baptist Hospital in Winston-Salem, North Carolina. QualChoice was one of three managed care organizations approved to offer a managed Medicare product in North Carolina at the time of initiation of this project. Both Medicare and commercial enrollees were included. Patients enrolled in 1998 in QualChoice with at least one diagnosis of CHF (ICD-9-CM code 428.x) in the encounter claims database were identified based on a single inpatient or outpatient encounter with the diagnosis in either the primary or secondary position. Age, gender, and Medicare coverage status were obtained from the enrollment database. Data were available for 1220 actively enrolled patients. QualChoice served an enrolled population base of over 69,000 in a 20-county area in northwest NC as of May 1998.

Program Description. The ACE project is a quality improvement effort focused on physician education and support of good practice patterns through use of performance audits with feedback and chart reminders. Intervention development for ACE was based on increasing awareness of identified gaps in care, motivating change, and demonstrating improvement. Following analysis of baseline data, physician performance reports and patient-specific reminders were generated and mailed to primary care physicians in the QualChoice network. The reports summarized practice guidelines for CHF, provided performance data for the physician in comparison to performance of the network, identified the specific patients with CHF, and requested reevaluation of the patient's diagnostic and/or therapeutic status. Patient-specific reminders were designed to prompt appropriate treatment of patients with CHF.

QualChoice of North Carolina, Inc. selected CHF—a high volume, high risk, chronic condition that is expected to become even more prevalent—as a pertinent clinical topic to focus on for the Quality Improvement System for Managed Care (QISMC). As a “Medicare+Choice” organization, QualChoice is required to initiate two Quality Assurance/Performance Improvement (QAPI) projects each year for QISMC. The ACE Project served as QualChoice's 1999 local (optional) QAPI project. Since the Health Care Financing Administration established CHF as the national topic for 2001, QualChoice participated in a statewide extension of Project ACE conducted jointly by Medical Review of North Carolina (MRNC) and Wake Forest University School of Medicine. In addition to improving processes of care, QualChoice aims to reduce the high rates of hospitalization and death related to CHF currently existing among “MedicareGOLD” (Medicare+Choice) enrollees.

Determination of Drug Utilization. Use of CHF medications was determined by query of the pharmacy claims database covering January 1, 1998, to December 31, 1998. In addition to ACEI, ARB, and BB, we also examined use of diuretics, digitalis preparations, and calcium channel blockers (CCB). During the study period, prescription drug coverage for both Medicare and commercial QualChoice members was provided at two levels of co-payment. For both groups, all prescription generic drugs were available for the lower co-payment, and all prescription brand name drugs were available for the same higher co-payment. The difference between generic and brand co-payment for Medicare members was \$8.00. The difference between generic and brand co-payment for commercial members varied based on benefit design, but it was no more than \$10.00 for any group. Medicare members' drug benefits were capped at \$200 per quarter.

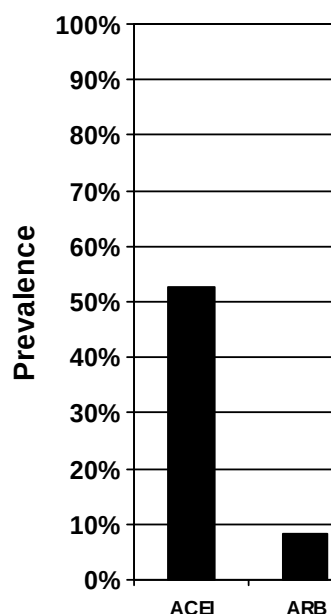


Figure 1. Prevalence of use of chronic heart failure-related medications during 1998 in the study population.

Table 1. Practice-level performance regarding the use of chronic heart failure-related medications during 1998.

CHF medications	Percentiles of practice performance				
	10 th (%)	20 th (%)	50 th (%)	80 th (%)	90 th (%)
ACE inhibitors (ACEI)	28.6	37.5	50.0	66.7	71.4
Angiotensin receptor blockers (ARB)	0.0	0.0	5.6	16.7	21.4
ACEI or ARB	33.3	40.0	54.2	70.0	77.8
Beta-blockers	7.7	14.3	21.4	36.4	40.0
Diuretics	50.0	56.5	66.7	80.0	89.3
Digitalis	14.3	16.7	30.0	40.9	54.5
Calcium channel blockers	16.7	20.0	30.4	40.9	52.4

Data Analysis. Characteristics of patients with CHF were summarized using the mean and standard deviation for continuous variables and proportions for categorical variables. Utilization of CHF-related medications was examined using two approaches. First, we calculated the simple proportion of individuals filling a prescription for a medication in a specified class. This straightforward approach does not reflect the correlated nature of these data for patients treated within a practice. In theory, patients treated within a practice are more likely to be treated similarly than are patients treated in different practices. Consequently, as a second approach, we calculated the proportion of CHF patients filling a prescription for a CHF-related medication

in a specified class within each practice. We described the distribution of these practice-level proportions using the 10th, 20th, 50th, 80th and 90th percentiles. Mixed logistic regression analysis was used to examine the association of medication use with age, gender, and Medicare status, adjusted for the within-practice correlation. All analyses were performed using SAS.

Results

Baseline Characteristics. The sample size of the population studied was 1220. There were 65 practices, plus one that is a composite of practices with fewer than 5 QualChoice CHF patients per practice (included 130 patients). The mean age of patients was 71 years $\pm$ a standard deviation of 12.2 years. Patient ages ranged from 22 - 98 years. Women accounted for 52.5% of the population, vs. 47.5% men. Medicare enrollees were 83.6% of the population; the remainder consisted of commercial enrollees (16.4%).

Drug Therapy. As shown in Figure 1, when medication use was examined across all practices, prescriptions for ACEI, ARB and BB were filled by 52%, 9% and 25% of patients, respectively. Also of interest, prescriptions for diuretics, digitalis preparations, and CCB were filled by 69%, 34%, and 32%, respectively.

Practice Profiling. As described in Table 1, the top 10% of practices treated over 70% of their patients with ACEI, whereas the bottom 10% of practices treated fewer than 30% of their patients with ACEI. For BB, the corresponding figures were 40% and less than 10%. Substantial variability was also seen across practices for use of other CHF-related medications. Figure 2 shows practice level use of ACEI which ranged from 0 to 87.5%.

Table 2 depicts the use of CHF-related medications by age, gender, and Medicare status. In this analysis, Age had an inverse relationship to use of ACEI and BB while use of digitalis increased with age. Women were more likely to use diuretics and CCB than men. Medicare status was also

associated with greater use of diuretics and digitalis (Table 2).

However, after accounting for practice level correlation and adjusting for the variables shown in Table 3 using mixed logistic models, the use of ACEI did not differ significantly by age, gender, or Medicare status. Use of BB was greater in Medicare beneficiaries than in commercial enrollees and decreased with increasing age. In comparison to men, women were more likely to receive diuretics and CCB. Digitalis use increased with increasing age.

Discussion

Half of patients with CHF were not receiving ACEI therapy, the therapy most clearly proven to reduce morbidity and mortality related to CHF across all NYHA classes. Furthermore, three-quarters of patients were not receiving BB therapy, a therapy convincingly demonstrated to alter the progression of CHF in patients with NYHA Class I through III symptoms. In contrast, CCB and digitalis have not been convincingly shown to reduce mortality in patients with CHF. Nevertheless, we found that utilization of CCB and digitalis exceeded that of BB in this population. These results confirmed our suspicion that the pattern of care observed among CHF patients within this managed care plan would provide opportunities for improvement. Furthermore, there was substantial variation in the utilization of therapies across primary care practices. These findings may be explained in part by the heterogeneous nature of patients with CHF. Some practices with many patients with renal failure, for instance, might have a lower utilization of ACEI for reasons that are entirely appropriate. Conversely, a high degree of variability in the care delivered across practices could reflect inconsistent quality of care.

Evidence in Support of Rationale. A very brief summary of the evidence garnered in the most important trials to date

Practice

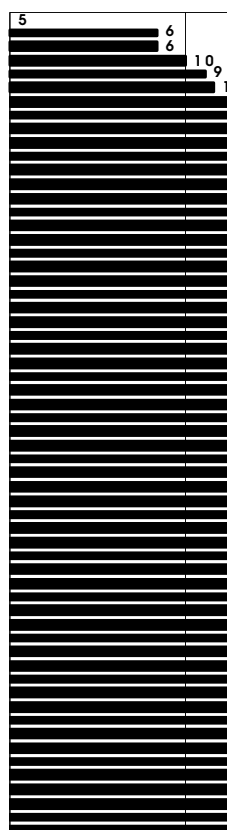


Figure 2. Use of angiotensin converting enzyme inhibitors by practice in 1998. Each practice is represented by a bar on the graph. The number of patients in each practice is listed to the right of the bar.

would include the V-HeFT I study, demonstrating a benefit of hydralazine/nitrate therapy and the V-HeFT II study, showing improved benefit with enalapril compared to hydralazine/nitrates.^{5,6} ACEIs have been shown beyond doubt to reduce morbidity and mortality in CHF. The CONSENSUS trial demonstrated a benefit of ACEI in severe CHF.⁷ The SOLVD trial showed benefit of ACEI in mild-moderate CHF.⁸ The ELITE trial provides the most important evidence in support of the use of angiotensin receptor blockers for CHF to date; however, the ELITE II trial did not reveal a significant benefit from the use of losartan compared to captopril.^{9,10} Hence, there was, at the time of this study, no broad consensus on the indications for ARB's except as an acceptable substitute for ACEI's for ACEI-intolerant patients. The RALES trial supports the use of spironolactone in NYHA Class III-IV patients already on ACEI.¹¹

Beta-adrenergic antagonists reduce morbidity and mor-

Table 2. Odds ratios for receipt of chronic heart failure-related medications by patient characteristics adjusted for within practice correlation.

	Odds Ratio	95% Confidence Interval		P value
ACE inhibitors (ACEI)				
Age (decile)	0.91	0.83	0.99	0.04
Gender (M/F)	0.89	0.66	1.18	0.42
Medicare (Y/N)	0.86	0.58	1.25	0.42
Angiotensin receptor blockers (ARB)				
Age (decile)	0.96	0.85	1.09	0.54
Gender (M/F)	1.21	0.81	1.79	0.35
Medicare (Y/N)	1.54	0.98	2.81	0.06
ACEI or ARB				
Age (decile)	0.90	0.82	0.99	0.03
Gender (M/F)	0.92	0.71	1.18	0.51
Medicare (Y/N)	0.99	0.68	1.43	0.94
Beta-blockers				
Age (decile)	0.88	0.80	0.95	0.01
Gender (M/F)	0.97	0.70	1.35	0.86
Medicare (Y/N)	1.03	0.76	1.48	0.85
Diuretics				
Age (decile)	1.11	0.99	1.24	0.07
Gender (M/F)	1.46	1.15	1.86	0.01
Medicare (Y/N)	1.45	1.03	2.05	0.03
Digitalis				
Age (decile)	1.18	1.09	1.28	0.01
Gender (M/F)	1.00	0.80	1.25	0.99
Medicare (Y/N)	1.75	1.30	2.37	0.01
Calcium channel blockers				
Age (decile)	0.98	0.90	1.08	0.73
Gender (M/F)	1.49	1.17	1.91	0.01
Medicare (Y/N)	1.10	0.84	1.44	0.51

tality in many CHF patients. The MERIT-HF trial, in patients with predominantly NYHA Class II and III heart failure, was halted on October 31, 1998, when the second interim analysis showed a 34% reduction in mortality in patients with predominantly NYHA Class II and III heart failure, confirming an hypothesis first proposed more than 25 years ago.^{12,13} The benefit of beta-blockers seen in all of the recent trials was seen in the presence of ACEI or ARB use. The use of the beta-blockers carvedilol and bisoprolol is also supported in heart failure.^{14,15} Although NYHA Class

IV patients did not unequivocally benefit from treatment in any of these published trials, the COPERNICUS trial, stopped prematurely in March 2000, demonstrated a benefit of carvedilol use in Class IV CHF patients. The BEST trial of bucindolol, another beta-blocker, revealed no difference in outcomes in the population as a whole and suggested that black patients had a specific lack of benefit from treatment with this beta-blocker. Since much of these data were not available at the time our practitioners were examined, we must acknowledge that we are holding them to standards that are shifting during the period of observation.

Diuretics are of known benefit in treating the symptoms of heart failure, including edema, and are used widely and generally. The Digitalis Investigation Group trial showed a benefit of digoxin on morbidity but not on mortality.¹⁶ However, calcium channel blockers are of less certain benefit to heart failure patients, excepting perhaps those with diastolic dysfunction due to hypertension and those with hypertrophic cardiomyopathy requiring a negative inotropic agent.

Limitations. The case selection method was chosen due to its positive predictive value. One of the authors noted in previous work that the addition of other ICD-9-CM codes indicating CHF did not add much to sensitivity and, in fact reduced specificity, resulting in inclusion of false positives.¹⁷ Although this case identification method allows inclusion of an unknown proportion of cases with diastolic dysfunction, distinguishing between these two groups (systolic vs. diastolic dysfunction) was beyond the scope of the current project. There also is no evidence that use of ACEI, ARB, and BB in patients with

diastolic dysfunction is harmful. In fact, beneficial effects of these medications were observed in patients with diastolic dysfunction in several recent, small clinical trials¹⁸⁻²¹ and one observational study.²²

In Perspective

The authors recognize the limitations of using only administrative data. The use of a more comprehensive medical record review would yield important information on comorbidities and the benefits of tailoring therapy to individuals. Although this is an important consideration, our goal was not to define CHF in the community, but rather to take patients defined as having CHF by community practitioners and to look at the utilization of drugs known to benefit patients similarly characterized in more rigorously controlled environments.

Data from previous studies are limited. Xuan et al defined the economic burden of CHF in a managed care population, and described utilization numbers not very different from ours. In their study, ACEI utilization in 1994 was slightly lower (38%)²³ than in our 1998 data (52%). Underutilization was also found in a study published in 1997, in which 41% of patients with CHF at a community health center were on ACEI.²⁴

Baseline results of the Achieving Cardiac Excellence Project demonstrate that many patients with CHF were not receiving medications proven to be effective in reducing morbidity and mortality and improving quality of life. In addition, substantial variability existed in the use of these medications across primary care practices within a network-model managed care organization. These findings confirmed our suspicion that there would be opportunities for improvement. The Achieving Cardiac Excellence Project is

Table 3. Multivariable adjusted* odds ratios for receipt of chronic heart failure-related medications by patient characteristics.

	Odds Ratio	95% Confidence Interval		P value
ACE inhibitors (ACEI)				
Age (decile)	0.91	0.78	1.06	0.21
Gender (M/F)	0.91	0.68	1.21	0.51
Medicare (Y/N)	1.05	0.57	1.92	0.89
Angiotensin receptor blockers (ARB)				
Age (decile)	0.84	0.68	1.03	0.10
Gender (M/F)	1.23	0.82	1.84	0.32
Medicare (Y/N)	2.18	1.06	4.49	0.03
ACEI or ARB				
Age (decile)	0.86	0.73	1.01	0.06
Gender (M/F)	0.94	0.73	1.21	0.65
Medicare (Y/N)	1.35	0.73	2.49	0.34
Beta-blockers				
Age (decile)	0.81	0.72	0.91	0.01
Gender (M/F)	1.01	0.72	1.42	0.97
Medicare (Y/N)	1.59	1.07	2.36	0.02
Diuretics				
Age (decile)	1.04	0.90	1.22	0.57
Gender (M/F)	1.43	1.12	1.83	0.01
Medicare (Y/N)	1.29	0.84	1.98	0.24
Digitalis				
Age (decile)	1.12	1.01	1.25	0.03
Gender (M/F)	0.96	0.77	1.18	0.69
Medicare (Y/N)	1.40	0.96	2.04	0.08
Calcium channel blockers				
Age (decile)	0.93	0.82	1.05	0.26
Gender (M/F)	1.51	1.18	1.92	0.01
Medicare (Y/N)	1.23	0.84	1.78	0.28

For each medication, the model included terms for age, gender, Medicare status, and practice.

focused on improving the quality of care provided within a managed care network rather than on identifying individual practitioners for inclusion or exclusion. Hence, we have focused on medical practices rather than individual practitioners. We are proposing standards of excellence based on population norms rather than on arbitrary standards set by external agencies. We believe that the baseline 90th percentile performance standards reported here are achievable in most,

if not all, of the practices in this network. We conclude that managed care organizations should develop, test and implement network level strategies designed to optimize the appropriate utilization of effective drug therapies for patients with CHF.

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ERRATUM

In the table of contents of the previous issue of the Journal (Volume 63:6), Dr. Leah Devlin was listed with an MD degree. Her degrees are DDS, MPH, as appeared correctly on the title page of her article. The editors regret the error.