Pharmacotherapy Management of Heart Failure in the Louisiana Medicaid Population

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Introduction and Background

Heart failure (HF) is a chronic disabling disease that occurs when the heart is unable to meet the metabolic demands of the body. This condition is characterized by symptoms of fatigue, decreased activity tolerance, and dyspnea. Heart failure affects an estimated 5 million Americans. Heart failure has a significant economic impact on the healthcare industry; it is the most common inpatient diagnosis for patients 65 years of age or older.[1] The Centers for Medicare and Medicaid Services estimates that $4 billion were expended on Medicare beneficiaries for HF-related services in 2001.[1]

It is likely that the number of patients with HF will continue to increase as the population ages, and as treatments for the conditions that lead to HF continue to reduce mortality. With this in mind, treatment of patients with HF should follow the published American College of Cardiology/American Heart Association (ACC/AHA) HF guideline. Its use has been associated with reduced morbidity and mortality in patients diagnosed with HF.[2] Previous articles in this series on HF have discussed the following: an overview of the guideline for treatment of HF, the role of vasodilators in HF, the role of beta blockers in HF, and the role of aldosterone receptor blockers in HF. This article will examine the guideline for treatment of HF and compare it to the actual treatment of Louisiana Medicaid recipients with HF.

HF in the Louisiana Medicaid Population – Methods

A secondary claims data analysis was performed to evaluate trends in HF prevalence in the Louisiana Medicaid population and to examine compliance with recommended prescribing. These data were obtained from the Louisiana Medicaid Program and paid claims for all Medicaid recipients from January 1, 1998, to December 31, 2003, and were examined to identify the HF study population.

For this study, ICD-9-CM codes were used to identify the population with HF. Identified recipients were then followed in six-month increments from January 1, 1998, until December 31, 2003. Medicaid recipients were identified for inclusion into a six-month study period if they met the following criteria:

1. Continuous eligibility for 6 months in any of the 12 study periods from January 1, 1998, until December 31, 2003, as determined from the Medicaid recipient file, and

2. At least one claim with a primary or secondary diagnosis of HF defined as ICD-9-CM codes 398.91 (Rheumatic heart failure, congestive) or 428 to 428.9 (heart failure).

After identification, recipients were then placed into 1 of 3 groups based on their age at the start of each six-month study period. The groups used were: 0 to 17 years of age, 18 to 64 years of age, and 65 years of age and older. Also, recipients were grouped based on paid prescription claims for HF-related drugs. For the purposes of this study, the following were considered HF-related drugs:

- ACE (Angiotensin Converting Enzyme) inhibitors
- ARBs (Angiotensin Receptor Blockers)
- Beta blockers
- Digoxin
- Spironolactone
- Other diuretics

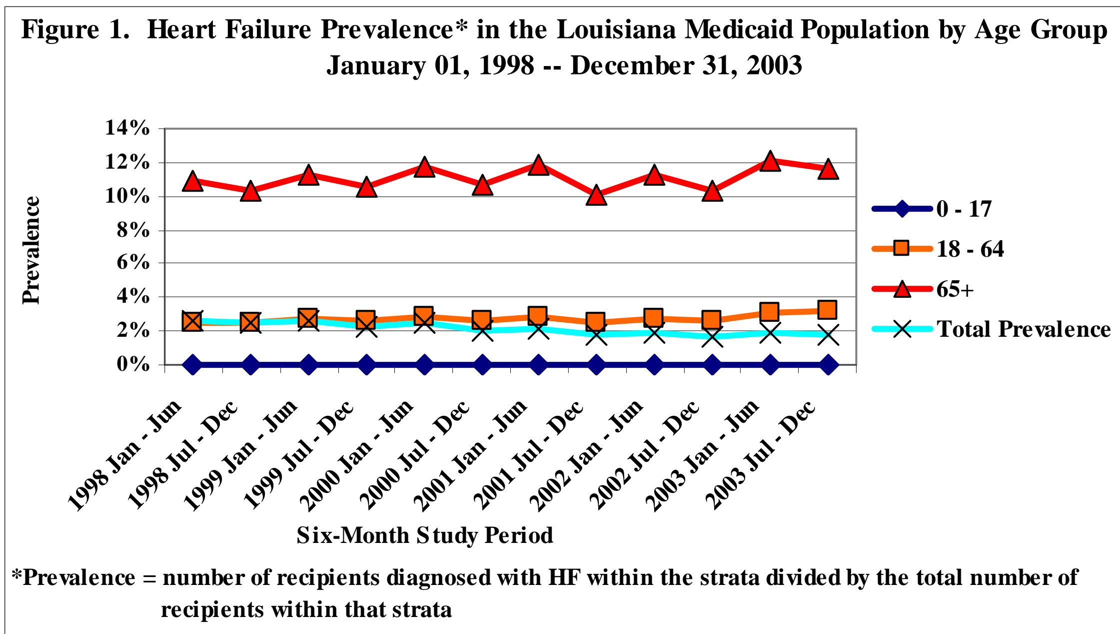
It is important to remember that HF may be a consequence of diastolic dysfunction (abnormal ventricular filling) and/or systolic dysfunction (reduced myocardial contractility). Of those individuals diagnosed with HF, it has been estimated that approximately 20% to 60% have

HF with relatively normal left ventricular ejection fraction (LVEF).[2] For this study, recipients were not sub-divided according to HF type. Therefore, as the results of this study are read, take into consideration that the recipients included are heterogeneous with regard to the pathophysiology of the diagnosed HF and that treatment regimens may vary according to type of HF diagnosed and other recipient-specific factors, such as presence of comorbidities.

HF in the Louisiana Medicaid Population – Results

Currently, it is estimated that HF affects 1.5 to 2% of the population, and its prevalence in Americans older than 65 years is 6 to 10%.[3] From 1998 to 2003, as noted in Figure 1, the prevalence of HF in Louisiana Medicaid recipients 65 years of age and older ranged from 10% to12%. In Louisiana, data from 2003 indicate that HF affected approximately 2% of the Medicaid population.

Figure 1. Heart Failure Prevalence* in the Louisiana Medicaid Population by Age Group January 01, 1998 -- December 31, 2003



*Prevalence = number of recipients diagnosed with HF within the strata divided by the total number of recipients within that strata

HF in the Louisiana Medicaid Population – Medication Utilization

The treatment guideline for HF strongly recommends the use of ACE inhibitors in all patients with HF due to left ventricular (LV) systolic dysfunction with reduced LVEF unless the patient has a contraindication or is unable to tolerate them.[2] Many clinical trials have

demonstrated the benefits of reduced morbidity and mortality for patients with HF who are taking an ACE inhibitor. Unfortunately, studies assessing the use of ACE inhibitors in patients with HF have shown a disappointing rate of use. In a 1994 study, Stafford et al. reported a national ACE inhibitor prescribing rate of 30.6% for patients with HF.[4] A review of ACE inhibitor use in Kansas Medicaid patients found that only 37.8% were receiving an ACE inhibitor.[5] Smith et al. found ACE inhibitors to be used in 36% of HF cases in 1994-1995.[6] Also, in a systematic review of articles assessing practice patterns, Bungard et al. found a median prescribing rate of 26% in the community setting.[7] The data for the Louisiana Medicaid population with HF showed that the percentage of patients prescribed an ACE inhibitor remained relatively constant during the period from 1998 to 2003. From visual inspection of Figure 2, it appears that ACE inhibitor usage trended around 42%. However, as noted in the literature, the

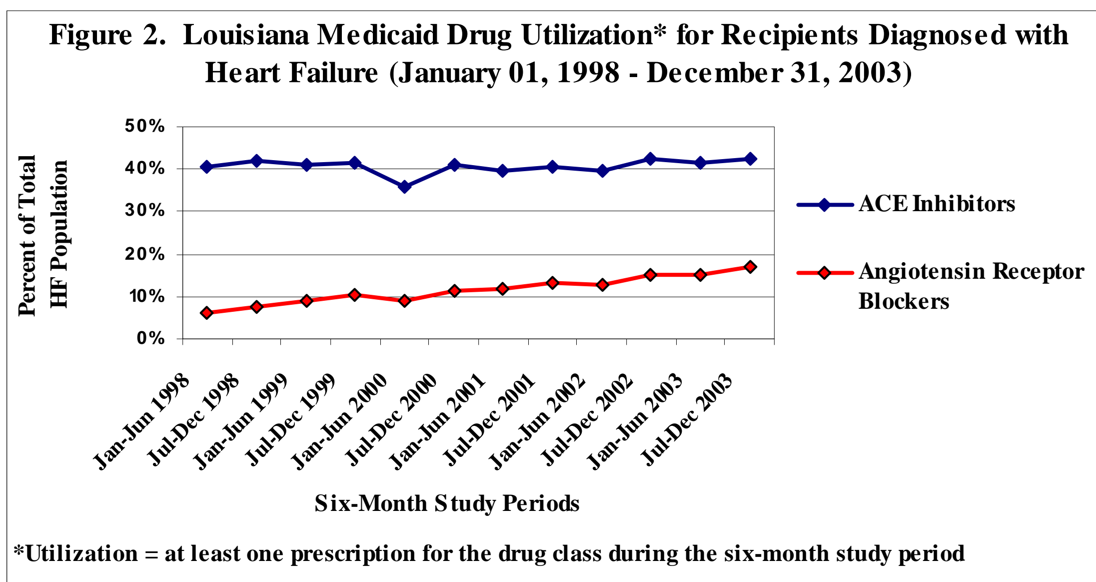


Figure 2. Louisiana Medicaid Drug Utilization* for Recipients Diagnosed with Heart Failure (January 01, 1998 - December 31, 2003)

*Utilization = at least one prescription for the drug class during the six-month study period

use of ACE inhibitor therapy is employed less frequently in patients with diastolic dysfunction HF when compared to systolic dysfunction HF.[8] Therefore, the percentage of appropriate ACE inhibitor utilization reported in this analysis is likely to be underestimated since not all of the recipients included in the study may have been candidates for ACE inhibitor therapy. Also, it can be noted from Figure 2 that ARB utilization from 1998 to 2003 showed an upward trend.

Research is ongoing to determine the role of ARBs in HF. According to the current ACC/AHA HF guideline, it is reasonable to consider an ARB in patients who are intolerant to ACE inhibitors because of cough or angioedma. Valsartan and candesartan have demonstrated benefit in reducing hospitalizations and mortality due to HF.[2] For those patients who are intolerant to ACE inhibitors due to hypotension or renal dysfunction, another consideration would be a combination of hydralazine and isosorbide dinitrate.[2]

Besides ACE inhibitors and ARBs, other medications should be considered for patients diagnosed with HF. As mentioned previously, systolic HF medication management may include: beta blockers, aldosterone receptor antagonists, diuretics, and digoxin. For patients diagnosed with HF with preserved LVEF, management is based on the control of blood pressure, heart rate, blood volume, and myocardial ischemia.[2] Figure 3 displays trends in utilization of medications other than ACE inhibitors and ARBs in HF treatment.

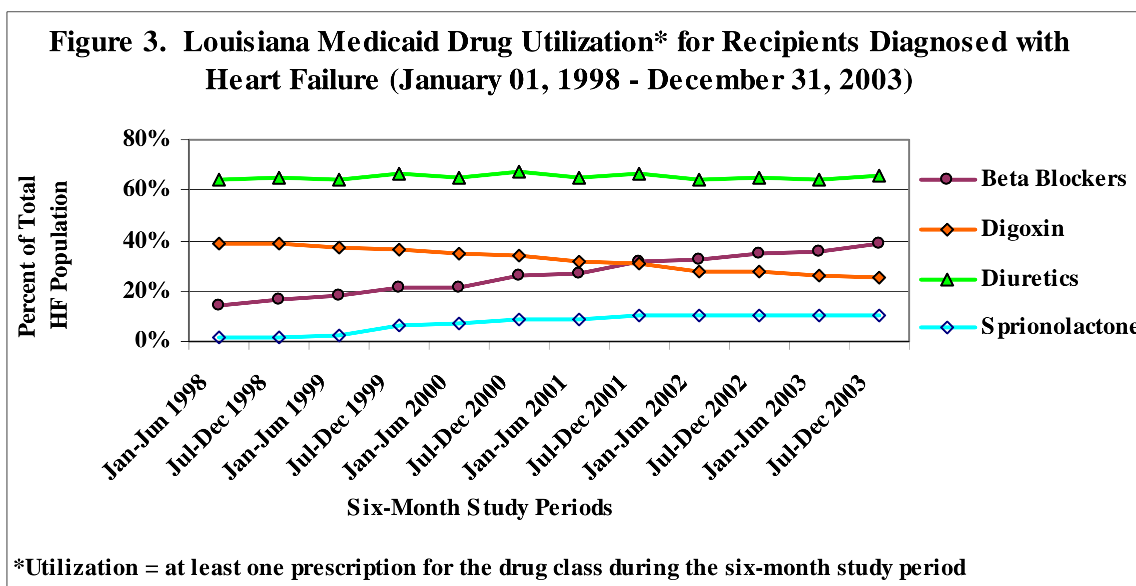


Figure 3. Louisiana Medicaid Drug Utilization* for Recipients Diagnosed with Heart Failure (January 01, 1998 - December 31, 2003)

*Utilization = at least one prescription for the drug class during the six-month study period

Beta blockers have been shown to reduce morbidity and mortality in patients with HF. The current guideline suggests beta blockers be prescribed for all patients with stable HF due to reduced LVEF unless a contraindication exists or the patient is unable to tolerate this class of medications.[2] A review of the patterns of medication use in patients participating in the SOLVD

trial showed beta blockers were used in 18% of patients.[9] Another recent study by Bouvy et al. showed prescribing rates for beta blockers in patients presenting to the hospital for HF increased from 11.3% in 1990 to 28.7% in 1998.[10] The Louisiana Medicaid data indicate that the use of beta blockers by recipients diagnosed with HF has increased from approximately 15% in 1998 to almost 40% in 2003.

The most recent recommendations for treatment of HF include the use of an aldosterone receptor antagonist, such as spironolactone. Spironolactone was shown to produce a 30% reduction in risk of death in patients with HF.[11] Spironolactone should be considered in carefully selected patients with moderately severe or severe HF symptoms and recent decompensation or with LV dysfunction early after MI.[2] Patients receiving spironolactone should be closely monitored for hyperkalemia.[2] The use of spironolactone in Louisiana Medicaid recipients diagnosed with HF has increased from approximately 2% in 1998 to 10% in 2003.

Diuretics, other than spironolactone, have long been used in HF to improve symptoms of fluid overload, exercise tolerance and cardiac function. The current guideline recommends the use of diuretics for patients with symptoms or prior history of fluid retention. Additionally, the use of these agents should continue once those symptoms improve. According to the guideline, loop diuretics are the preferred diuretic agents for use in most patients diagnosed with HF. However, the guideline indicates that thiazide diuretics may be appropriate for hypertensive HF patients with mild fluid retention because they confer more persistent effects.[2] Sixty-two percent of patients enrolled in the SOLVD trial were receiving diuretics.[9] The use of diuretics by Louisiana Medicaid recipients diagnosed with HF has remained steady during the study period, with prescribing rates of 63% in 1998 to 65% in 2003.

Digoxin has been used in HF to improve symptoms, quality of life, functional capacity, and exercise tolerance. Only one clinical trial has evaluated long-term therapy, and it failed to

show a mortality benefit.[2] Currently, digoxin is recommended for patients with continuing symptoms of HF already receiving an ACE inhibitor (or ARB), beta blocker, and diuretics.[2] Digoxin was taken by 45% of patients enrolled in the SOLVD trial.[9] The use of digoxin by the Louisiana Medicaid HF population has declined from 39% in 1998 to 25% in 2003.

The bar chart in Figure 4 shows prescribing patterns by monotherapy, combination therapy, or no prescribed therapy for recipients diagnosed with HF. The percentage of patients receiving a combination of at least one medication from all the classes in the study (ACE inhibitor or ARB, beta blocker (BB), diuretic, digoxin, and spironolactone) has increased from 1998 to 2003. The combination of an ACE inhibitor or ARB, beta blocker, and diuretic has increased from approximately 3% in 1998 to 12% in 2003. It appears from the bar chart that the use of medication combinations that included spironolactone increased over the study period. Even though a decrease (from 14% in the 1998 to 9% in 2003) in the use of diuretics as a monotherapy occurred during this study period, diuretics remained the most prescribed monotherapy for HF in the Louisiana Medicaid HF population. The bar chart also shows that the prescribed combination therapy of a diuretic, beta blocker, and spironolactone has increased, while the use of the combination of an ACE inhibitor or ARB and digoxin has decreased. The percentage of HF recipients not receiving therapy appears to have remained relatively stable with a slight downward trend from 21% in 1998 to 19% in 2003.

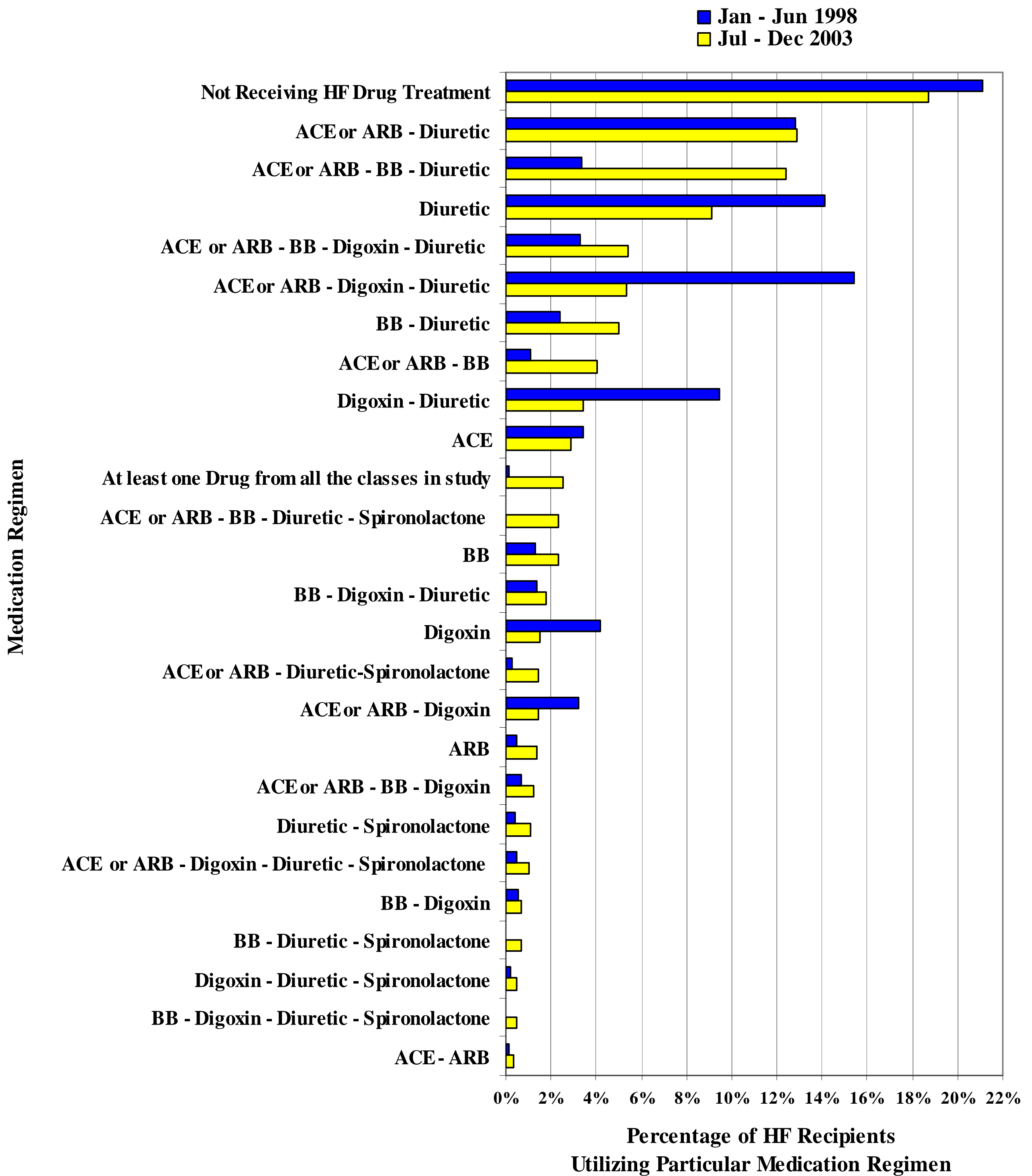


Figure 4. Louisiana Medicaid Drug Utilization* for Recipients Diagnosed with Heart Failure
1998 Compared to 2003
*Utilization = at least one prescription for the drug class during the six-month study period
Jan - Jun 1998
Jul - Dec 2003
Not Receiving HF Drug Treatment
ACE or ARB - Diuretic
ACE or ARB - BB - Diuretic
Diuretic
ACE or ARB - BB - Digoxin - Diuretic
ACE or ARB - Digoxin - Diuretic
BB - Diuretic
ACE or ARB - BB
Digoxin - Diuretic
ACE
At least one Drug from all the classes in study
ACE or ARB - BB - Diuretic - Spironolactone
BB
BB - Digoxin - Diuretic
Digoxin
ACE or ARB - Diuretic-Spironolactone
ACE or ARB - Digoxin
ARB
ACE or ARB - BB - Digoxin
Diuretic - Spironolactone
ACE or ARB - Digoxin - Diuretic - Spironolactone
BB - Digoxin
BB - Diuretic - Spironolactone
Digoxin - Diuretic - Spironolactone
BB - Digoxin - Diuretic - Spironolactone
ACE - ARB
Medication Regimen
0% 2% 4% 6% 8% 10% 12% 14% 16% 18% 20% 22%
Percentage of HF Recipients
Utilizing Particular Medication Regimen

Conclusion

For the study period from January 1, 1998, through December 31, 2003, pharmacotherapy treatment of Louisiana Medicaid recipients diagnosed with HF compared positively in most instances to utilization statistics reported in published research. During the study period, this analysis showed that (1) ACE inhibitor utilization remained stable while the use of ARBs increased; (2) beta blocker and spironolactone utilization increased; (3) diuretic utilization was stable and was the most frequently prescribed HF monotherapy; and (4) digoxin utilization decreased.

Heart failure has become a common disorder. Heart failure is not a disease limited only to the geriatric population. However, since the population is aging and heart failure is more prevalent in older patients, published management guidelines shown to reduce morbidity and mortality in patients diagnosed with heart failure become increasingly important.

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