

Abstract

Introduction: Despite advances in cardiovascular care, heart failure (HF) remains a major health problem decreasing survival, impairing quality of life, and requiring frequent hospitalizations. Clinical guidelines provide a summary of best evidence for the management of HF, but not all clinical practice reflects these recommendations. **Rationale:** An administrative claims database offers a unique glimpse into real world management of HF. We analyzed pharmacological treatment of patients diagnosed with HF prior to the publication of AHA(2005) and HFSA (2006) guidelines and after availability of guidelines to determine patterns in pharmacological management of HF. **Methods:** We evaluated 6 month HF medication prescriptions in two cohorts of patients: Cohort A, identified in January 1- June 30, 2005 [prior to the publication of ACC/AHA and Heart Failure Society of America (HFSA) guidelines] and Cohort B, identified in October 1, 2006-March 31, 2007 (post guideline publication). Baseline characteristics and use of combination therapies are reported for both cohorts and those with moderate/severe disease in each time period. Patients with one or more admissions for HF or dyspnea in the 6 months prior to study inclusion were considered to have moderate/severe HF. **Results:** The mean \pm SD age for both cohorts A (n= 29,784) and Cohort B (n= 33,598) was 74 \pm 11. In both cohorts 50 % of patients were female, 9% of Cohort A and 7% of Cohort B patients were classified as moderate-severe HF. Cohort B patients were more likely than Cohort A patients to be prescribed angiotensin receptor blockers (ARBs -14% vs. 11%) and Beta blockers (BBs -41% vs.37%). Similarly, for the subgroup with moderate to severe disease, patients in Cohort B were more likely to be prescribed (ARBs) (12% vs. 10%) and (BBs) (37% vs 34%) after hospitalization or outpatient therapy for acute HF. Except for BB and ACEI combination, there was no difference between the 2 subgroups of moderate-severe patients in the prescription of combination therapies. **Conclusions:** HF guidelines recommend the use of combination therapy for patients with moderate/severe disease. Although the intent of guidelines is to influence care models, in the real world only small differences in prescribing practices are noted before and after the publications of such guidelines.

Background

Heart Failure is a prevalent condition with significant health and economic consequences. National guidelines recommend the use of specific medications in combination therapy for the management of moderate to severe HF. A claims database provides a real life opportunity to observe trends in prescription of HF medications, adherence and health care utilization.

Objectives

To describe pharmacological treatment of HF patients prior to the publication of AHA (2005) and HFSA guidelines (2006) and after availability of such guidelines.

Methods

- We performed a retrospective cohort analysis of a nationwide administrative claims database with greater than 3 million members insured.
- We evaluated 6 month HF medication prescriptions in two cohorts of patients: **Cohort A**, identified in **January 1- June 30, 2005** [prior to the publication of ACC/AHA and Heart Failure Society of America (HFSA) guidelines] and **Cohort B**, identified in **October 1, 2006-March 31, 2007** (post guideline publication). The index date was defined as the date of diagnosis or hospitalization for HF during the identification periods.
- Patients were included if they were \geq 45 years old, had 12 months of continuous enrollment (6 months pre and 6 months post index date) and had a claim for HF (ICD9 Codes: ICD-9 codes: 402.11, 402.91, 404.11, 404.91, 428.0, 428.1, 428.2, 428.21, 428.22, 428.23, 428.4, 428.41, 428.42, 428.43 and 428.9) during study period.
- Proportion of patients, who were prescribed HF medications (Table 2) either individually or in combination are reported.
- Other outcomes of interest included medication adherence measured as medication possession ratio (MPR), all cause and HF specific hospitalizations, ED and outpatient physician visits during 6 month follow-up.
- Comparisons were made between Cohort A and Cohort B, and the subset of patients with moderate-severe HF within each cohort.
- Medication possession ratio (MPR), a measure of drug adherence, was defined as the sum of the days' supply of medication divided by the number of days between the first fill and the last refill plus the days' supply of the last refill.
- In the absence of clinical history and echocardiography, HF severity was based on 6 month pre-index date healthcare utilization. Patients with one or more HF specific hospitalizations were classified as having moderate-severe HF.

Results

Table 1. Patient Characteristics

Characteristic	Cohort A N=29784	Cohort B N=33598	P
Age *	75 \pm 11	74 \pm 11	<0.0001
Gender – Female, n(%)	14796 (50)	16803 (50)	NS
Type of Health Insurance, n(%)			<0.0001
Medicare	24344 (82)	30549 (91)	
HMO	2836 (10)	1161 (4)	
PPO	1860 (6)	1297(4)	
HF Severity			<0.0001
Mild	27245 (92)	31315 (93)	
Moderate-severe	2539 (9)	2283 (7)	
Co-morbidity, n(%)			
Diabetes	14548(49)	16558 (49)	NS
COPD	7999 (27)	8926 (27)	NS
Peripheral Vascular Disease	4541 (15)	5555 (17)	<0.0001
Cerebrovascular Disease	3920 (13)	4318 (13)	NS
Renal Disease	3300 (11)	5028 (15)	<0.0001

Table 2. HF Medication Prescribed

Medication	Cohort A N(%)	Cohort B N(%)	P
ACE Inhibitors (ACEIs)	12811 (43)	14776 (44)	0.01
Beta Blockers (BB)	10901 (37)	13639 (41)	<0.01
Isosorbide dinitrate (ISDN)	6280 (21)	6894 (21)	NS
Angiotensin Receptor Blockers (ARBs)	3008 (10)	4378 (13)	<0.01
Hydralazine (HYD)	865 (3)	1378 (4)	<0.01
Combination Therapy			
BB + ACEI or ARB	6797 (23)	8179 (24)	<0.01
BB + ISDN + ACEI or ARB	2108 (7)	2361 (7)	NS
BB + HYD + ACEI or ARB	263 (0.9)	432 (1)	<0.01
BB + HYD + ISDN	218 (0.7)	328 (1)	<0.01

•Patients with moderate-severe HF in either cohort were more likely to receive ACEI, ISDN, hydralazine and combination therapy compared with those with mild disease. There were no differences in the prescription of B blockers.

• In the subgroup of patients with moderate-severe HF, Cohort B patients were more likely to be prescribed ACEI (51% vs. 48%), ARBs (14% vs. 11%), B blockers (40% vs. 35%), and hydralazine (7% vs. 5%). Cohort B patients with moderate-severe disease were more likely to receive B-Blockers/ACEI or ARB in combination (27% vs. 23%). There were no differences in the prescription of other combination therapies.

•The MPR for individual medications were all > 0.80.

Discussion and Conclusions

•In this large retrospective analysis of patients diagnosed with HF, the majority had mild disease based on 6 month hospitalization rates prior to index date.

•Adherence, as measured by MPR, for all drug categories was good (MPR > 0.8 considered acceptable persistence of use).

•It is encouraging that patients in Cohort B (post publication of guidelines) were more likely to be prescribed ACEI, BB, ARBs, HYD and combination therapies.

• However, in the subgroup of patients with moderate-severe HF, there was little difference in prescription of most combination therapies between the two time points. Furthermore, at most, only 41% of patients with moderate-severe HF were receiving combination therapy, despite guideline recommendations.

•HF guidelines recommend the use of combination therapy for patients with moderate-severe disease. Although the intent of guidelines is to influence care models, in the real world only small differences in prescribing practices are noted before and after the publication of such guidelines.

Study Limitations

•Retrospective analysis of claims database intended for administrative use has inherent limitations in terms of disease classification and conclusions about patient adherence.

•HF severity score was based on at least one HF hospitalization during 6 months pre-index date and not based on EF or patient symptoms. This may have led to misclassification of HF severity in this population.

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