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Mini Review

A Study to Assess Limitations in the Adherence to 2013 American College of Cardiology Foundation/American Heart Association Practice Guideline for Management of Heart Failure in Primary Care

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Abstract

Background: Adherence to evidence-based American College of Cardiology Foundation/American Heart Association (ACCF/AHA) guideline for management of chronic heart failure (HF) has shown to be associated with improved outcomes. We sought to assess the limitations in the adherence to the guideline in our primary care clinic.

Methods: Electronic medical records (EMR) of chronic HF patients with at least 3scheduled consecutive visits to primary care physician (PCP) office within past 2 years at a family medicine residency program were reviewed in a retrospective observational study. Data from the most recent clinic visit was analyzed to assess limitations associated with adherence to the2013 ACCF/AHA guideline directed medical and device therapy.

Results: Analysis included 155 patients. There were 73(47.1%) patients with heart failure with reduced ejection fraction (HFrEF) and 82(52.9%) patients with heart failure with preserved ejection fraction (HFpEF). In HFrEF group, 51 (86.4%) patients were on HF specific beta blockers (BB), 44 (60.3%) were on angiotensin converting enzyme inhibitors/angiotensin receptor blockers (ACEI/ARBs), 7(9.6%) were on spironolactone. Maximal tolerable dose was achieved only in 8(13.6%) patients with BBs, 24(66.7%) patients with ACEIs,1(12.5%) patient with ARBs and 5(25%) patients with spironolactone. Despite clinical indication as per the guideline, implantable cardioverter defibrillator (ICD) was not used in 35(77.8%) patients and cardiac resynchronization therapy (CRT) was not used in 15(83.3%) patients. In patients with HFpEF, optimal BP (SBP<150/90 mm Hg) was achieved in 72 (87.8%) patients. Documentation of individual patient level factors such as tolerance, compliance, and insurance-related factors that potentially limit adherence to the guideline, was not readily available.

Conclusions: There appears to be a lag in the evidence for adherence to the 2013 ACCF/AHA guideline for management of chronic HF in Primary Care. System improvement measures should be implemented to improve documentation of management decisions made. Documentation should acknowledge consideration of recommended guidelines & provider's rationale for adhering or deviating from them.

ABBREVIATIONS

ACCF/AHA: American College of Cardiology Foundation/ American Heart Association; HFpEF: Heart failure with preserved Ejection Fraction; HFrEF: Heart Failure with reduced Ejection Fraction; BMI: Body Mass Index; DM: Diabetes Mellitus; CAD: Coronary Artery Disease; HTN: Hypertension; eGFR: estimated Glomerular Filtration Rate; BB: Beta Blockers; ACEI: Angiotensin Converting Enzyme Inhibitor; ARB: Aldosterone Receptor Blocker; BiDil: Isosorbide Dinitrate/hydralazine Hydrochloride; ICD: Implantable Cardioverter Defibrillator; CRT: Cardiac Resynchronization Therapy; GDMT: Guideline-Directed Medical Therapy; NYHA: New York Heart Association ; SCD: Sudden Cardiac Death; LBBB: Left Bundle Branch Block

INTRODUCTION

Heart failure (HF) has grown to epidemic proportion with approximately 650000, new cases diagnosed annually[1] and a prevalence increased from 90 to 121 per 1000 Medicare beneficiaries from 1994 to 2003[2]. Both HFrEF and HFpEF have been shown to equally contribute to the HF syndrome [3]. HF has become a public health problem with 50% absolute mortality

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within five years of diagnosis [4], greater than one million hospitalizations annually [1], 30-day all cause readmission rate of 25% [5] and an annual estimated cost of care exceeding $30 billion in the United States [1].

2013 ACCF/AHA guideline for HF recommendations

2013 ACCF/AHA guideline for HF provides comprehensive evidence-based recommendations for the management of HF stage A to D and device therapy for HF stage B to D [6]. In the current study we focused on HF stage C.

Stage C HF comprises patients with structural heart disease and prior or current symptoms of HF. Class I recommendations include patient education on HF self-care [7], ACEI use in all patients with HFrEF [8,9], ARB use in HFrEF when ACEI is intolerable [10,11], HF specific BB use in all patients with HFrEF [12-15]. Aldosterone antagonists are recommended in patients with New York Heart Association (NYHA) functional class II-IV symptoms with EF≤ 35% [16], in diabetic patients with history of MI with HF symptoms and EF ≤ 40% [17]. The combination of Hydralazine and Isosorbide dinitrate (BiDil) is recommended in African Americans (AA) with HFrEF and NYHA functional class III–IV symptoms despite optimal medical therapy [18,19]. Diuretic use and chronic oral anticoagulation is recommended in appropriate clinical setting [20,21]. Class IIa recommendations include exercise training to improve functional capacity [22], and use of continuous positive airway pressure (CPAP) to improve LVEF and functional status in patients with concomitant obstructive sleep apnea (OSA) [23]. Class I recommendation for device therapy include ICD for primary prevention of sudden cardiac death (SCD) in selected patients with HFrEF who are at least 40 days post-MI with LVEF ≤ 35% and NYHA functional class II or III symptoms [24,25], or patients with LVEF ≤ 30% and NYHA class I symptoms [26], while on optimal medical therapy and who are expected to live >1 year. CRT with defibrillator device is recommended for patients with LVEF ≤ 35%, sinus rhythm, left bundle branch block (LBBB) with a QRS ≥ 150 ms and NYHA functional class II or III symptoms or ambulatory class IV symptoms despite optimal medical therapy [27,28].

Class I recommendation in HFpEF include systolic and diastolic BP control in accordance with published clinical practice guidelines to prevent morbidity [29,30] and diuretic use for symptom relief.

Adherence to 2013 ACCF/AHA guideline for management of HF has shown to be associated with improved outcomes in patients with chronic HF[6].We sought to evaluate the guideline adherence and limitations in adherence in our clinic.

Pre-specified definitions

Definitions for HFpEF and HFrEF were LVEF ≥ 50% and LVEF<50% respectively [6]. Medical therapy was defined as suboptimal in HFrEF when maximal tolerable dose at the most recent clinic visit was <75% of the guideline recommended dose. Recommended maximal tolerable medical therapy in HFrEF for ACEI is: lisinopril, enalapril, quinapril and fosinopril20 mg/day, captopril150 mg/day and ramipril 10 mg/day. For ARB: valsartan320 mg/day and losartan100 mg/day. For BB: metoprolol succinate and metoprolol tartrate200 mg/day, carvedilol50 mg/day, carvedilol phosphate extended release80 mg/day andbisoprolol10 mg/day. Recommended dose for spironolactone 50 mg/day. Recommended dose for BiDil: 300 mg/day for Hydralazine and 120 mg/day for Isosorbide dinitrate. In HFpEF, medical therapy was considered suboptimal when the BP was >150/90 mm Hg. Although there is no specific target blood pressure defined in HFpEF, we chose a target BP<150/90 mm Hg based on JNC 8 guidelines [31]. Permissible hemodynamics and renal function to consider up-titration of medical therapy in HFrEF defined as systolic BP of ≥ 100 mm HG, resting HR ≥ 70 bpm and/or a serum creatinine< 3 mg/dL respectively.

METHODS

Study was approved by the local institutional review board which waived the consenting process, based on less than minimal risk to patient safety and privacy. EMRs of patients with chronic HF were reviewed starting from their most recent clinic visit to at least three consecutive visits in retrospect. The rationale for three visits was to give an opportunity to achieve maximal tolerable optimal medical and device therapy. Limitations in adherence to 2013 ACCF/AHA guideline for HF [6] in individual patients were assessed in following clinical indicators.

We assessed the proportion of HFrEF patients on guideline directed medical therapy, proportion of patients with maximal tolerable medical therapy in terms of HF specific BB, ACEI/ARB and aldosterone antagonist and AA patients on BiDil and appropriate device therapy in terms of ICD and CRT when indicated [27,28]. Proportion of HFpEF patients with optimal BP control as defined above were assessed. In both HF phenotypes, we assessed the proportion of patients who had optimal hemodynamic status, who received 60 minutes HF self-care education at post-hospital discharge, saw their PCP within seven days of hospital discharge, who were current with pneumococcal and influenza vaccination status and used CPAP if diagnosed with OSA.

Statistical analysis

IBM-SPSS version 22, Chicago, IL was used for the statistical analysis. Analysis was primarily exploratory to describe the cohort characteristics and express proportion of patients with guideline adherence. Categorical variables were expressed as frequencies and proportions and continuous variables as mean ± standard deviation.

RESULTS

Cohort consisted 163 patients with chronic HF. Eight patients were excluded for lack of adequate clinic visits, resulting in 155 patients for the analysis. Mean (± SD) age of the cohort was 62.5(±12.9) years and 65(41.9%) were females. Patients with HFpEF dominated the cohort compared to HFrEF (82(52.9%) Vs. 73(47.1%); P=0.0001). Baseline characteristics are shown in Table (1).

In evaluating guideline adherence in HFrEF we found that there were51(86.4%) patients on HF specific BB, 44(60.3%)patients on ACEI/ARBs, 7(9.6%) patients on spironolactone and one AA patient was on Bidil. NYHA functional class was not routinely documented to determine whether appropriate therapies and/or up-titration of dose were considered. Guideline recommended maximal tolerable dose was achieved only in 8(13.6%) patients

Table 1: Baseline characteristics (N=155).

Parameter	HFrEF; N=73 (47.1%)	HFpEF N= 82 (52.9%)
Age (±SD) years	62.5 (±12.9)	64.4±12.5
LVFF (±SD) %	31.0 (8±10.3)	58.8±4.4
SBP (±SD) mm HG	132.6±25.4	128.5±20.6
DBP (±SD) mm HG	76.2±13.6	73.7±11.7
HR (±SD) beats/min	79.5±13.3	76.9±10.6
Serum Na (±SD) mEq/dL	137.3±4.2	137.1±4.9
Serum BUN (±SD) mg/dL	29.3±24.3	27.6±21.4
Serum Cr (±SD) mg/dL	1.6±1.2	1.9±2.1
eGFR (±SD) ml/min/1.23 m^2	56.1±30.0	54.2±27.8
BNP (±SD) ng/dL	868.9±1213.5	497.9±580.0
BMI (±SD) Kg/m^2	32.3±8.5	34.6±11.9
A1C (±SD)	7.2±1.4	7.6±2.2
Female	30 (41.1%)	35 (42.7%)
DM	41 (56.2%)	43 (52.4%)
HTN	65 (89.0%)	74 (90.2%)
CAD	46 (63.0%)	54 (65.9%)
Dyslipidemia	50 (68.5%)	50 (61.0%)
AF	14 (19.2%)	20 (24.4%)
OSA	7 (9.6%)	6 (7.3%)
Smoking	26 (35.6%)	27 (32.9%)
Aspirin	18 (24.7%)	18 (22.0%)
Statin	18 (24.7%)	27 (32.9%)
BB	28 (38.4%)	32 (39.0%)
ACEI	36 (49.3%)	44 (41.5%)
ARB	4 (5.5%)	3 (3.7%)
Aldactone	7 (9.6%)	4 (4.9%)
Diuretics	17 (23.3%)	24 (29.3%)
Metformin (in DM)	32 (43.8%)	32(39%)
Insulin (in DM)	2 (4.8%)	16 (19.5%)
Anticoagulation	8 (11.0%)	11 (13.4%)

with BB, in 24(66.7%) patients with ACEI, in 1(12.5%) patient with ARB and in 5(25%) patients with spironolactone. These statistics were in patients with permissible hemodynamics and serum creatinine which would have allowed up-titration of the medication dose. ICD was not used in 35(77.8%) patients and CRT was not used in 15(83.3%) patients despite a clinical indication per the guideline [27,28,30].

In patients with HFpEF, adherence to the guideline of optimal BP control (< 150/90 mm Hg) was achieved in 72(87.8%) patients. In HFrEF 55(75.3%) patients had BP <150/90 mm Hg, but only 23(31.5%) patients had HR ≤ 70. Unadjusted all-cause deaths were 13% and 18% in patients with HFrEF and HFpEF respectively (P=0.43).

Guideline adherence was acceptable in terms of prompt PCP visit scheduling within seven days of hospital discharge (100%) and pneumococcal immunization 115(74.2%). However, influenza immunization varied between 12% to 70% with decline in recent seasons. Documented LVEF and an EKG within past year present in 129(83.2%) and 146 (94.2%) patients respectively. Diabetes was present in 84(54.2%) patients and 62(73.8%) off these were on metformin therapy. Average diabetes control was acceptable with a mean HbA1Cof 7.2. Chronic AF requiring anticoagulation as per the guidelines [20,21], was present in 44(28.3%) patients. Only 15(34.1%) patients were on an anticoagulation agent. Reasons for lack of anticoagulation were not documented in at least 50% of the cases. OSA was present in 13(8.4%) patients. CPAP use was less than 50% in this group. Documentation of a referral for formal exercise training, cardiac rehabilitation, NYHA functional classification and scheduled device interrogations in patients with ICD and CRT therapy were not readily available.

DISCUSSION

Principal finding of our analysis is that, there appears to be inconsistency in documentation of the provider's consideration for the guideline directed therapies and reasons for not applying in certain patients with chronic HF. This may contribute to the perception that there is lack of adherence and failure to consider in future appropriate management options. Documentation for guideline adherence was acceptable of initiation of BB but fell short in terms of initiation of ACEI/ARB in HFrEF. Most importantly, there was inconsistent documentation that up-titration was considered. Initiation and up-titration to maximal tolerable dose are equally important to derive the morbidity and mortality benefits demonstrated in RCTs [6]. Adherence to the guideline was acceptable regarding scheduling post hospital office visit and being current with pneumococcal vaccine. The percentage of patients current with receiving Influenza immunization was below the guideline accepted level. Suboptimal influenza immunization rate was most commonly due to patient refusal. Blood Pressure was optimally controlled in HFpEF. Our study is in accordance with recent study by Komajda et al. [32], where significant lag in guideline adherence was noted in optimal medication dosing in patients with chronic HF. Our study fills the gap in the evidence by providing information on the perception that there is lack of adherence in primary care practice and in the United States patient population.

Primary care provider is the cornerstone in optimizing medical care, coordinating care, disease progression surveillance and in making timely referrals to sub-specialists as needed. Up-titration of guideline directed medical therapy requires close monitoring of hemodynamics, symptoms, functional assessment, volume status and diagnostic studies which require frequent visits. Primary care physician plays a crucial role, in disease management and up-titration because seeing a specialist at closer intervals may not be practical. Therefore, it is crucial to empower the primary care provider to improve the quality of care in chronic heart failure.

Patient related factors for perceived non adherence to guideline are multifactorial. It has been documented that many patients do not tolerate the doses of neurohormonal antagonists documented in the trials, despite vigorous efforts [33]. Patient

non-compliance with clinic visits, diagnostic testing and keeping up with sub-specialists could negatively affect the guideline adherence. Primary care physician is less likely to up-titrate medication dose in a stable, asymptomatic HF patient because of potential concern about tipping the balance of cardio-renal homeostasis. Patient level factors which contribute to suboptimal therapy include lack of knowledge on their disease and its natural course, lack of insurance coverage for certain medications, failure to adequately address co morbid conditions. Scheduling closer appointments with primary care physician will help with up-titration of medication, with monitoring NYHA functional class, detecting EKG changes and assessing LVEF. These are key variables that prompt escalation of the medical and device therapy when indicated.

System improvement measures after the analysis

Measures were initiated to educate resident physicians on updated HF practice guidelines [6,34], proper assessment and documentation of NYHA functional class at every clinic visit and on recommendations for periodic echocardiographic and electrocardiographic surveillance. Measures were initiated to refer patients to cardiac rehabilitation and have our local hospital participate with the American Heart Association Get With The Guidelines-Heart Failure (AHA GWTG-HF) [6], Program to improve quality of care in CHF in-patients.

Limitations

Our study results should be interpreted in the context of following limitations. The study was limited to one primary care office with a low sample size, predominantly consisting of patients with Medicare. Therefore, may not be applicable to other clinical settings with different insurance coverage. The retrospective nature of the study could have resulted in unmeasured confounding variables and some degree of selection bias that could have affected some of the results. Patient's race was not documented on most of the patients to determine the race based indication of BiDil in AA patients with HFrEF [18,19]. Many patients were also seen by cardiologists as outpatients. Dynamic changes in therapy by cardiologists were not always accessible which could have affected the study results. Medication tolerance was only defined in terms of hemodynamics and renal function. Data on patient reported symptoms were not documented consistently. So it is unknown how much it contributed to the results. Similarly, data on Insurance limitations, patient compliance and preference was not available which can limit the use of optimal medical therapy. BB use for other indications other than HF such as prophylaxis for refractory migraine and variceal bleed prevention and spironolactone use for hyperaldosteronism could have inadvertently influenced hemodynamics, limiting the up-titration of optimal HF therapy.

CONCLUSION

There appears to be a lag in the evidence for adherence to the 2013ACCF/AHA guideline for management of chronic HF in Primary Care. System improvement measures should be implemented to improve documentation on consideration of guidelines and limitations in individual patients so as to improve the guideline adherence.

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