Influence of dedicated heart failure clinics on delivery of recommended therapies in outpatient cardiology practices: Findings from the Registry to Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting (IMPROVE HF)

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Background National guidelines recommend heart failure (HF) disease management programs to facilitate adherence to evidence-based practices. This study examined the influence of dedicated HF clinics on delivery of guideline-recommended therapies for cardiology practice outpatients with HF and reduced left ventricular ejection fraction.

Methods IMPROVE HF, a prospective cohort study, enrolled 167 cardiology practices to characterize outpatient management of 15,381 patients with chronic systolic HF. Adherence to guideline-recommended HF therapies was recorded, and the presence of a dedicated HF clinic was assessed by survey. Multivariate models identified contributions to delivery of guideline-recommended HF therapies.

Results Of practices, 41.3% had a dedicated HF clinic. Practices with a dedicated HF clinic had greater adherence to 3 of 7 guideline-recommended HF therapy measures: angiotensin-converting enzyme inhibitor/angiotensin receptor blocker (P = .02), β-blocker (P = .025), and HF education (P = .009). After adjustment, use of a dedicated HF clinic was associated with greater conformity in 2 of 7 measures: cardiac resynchronization therapy (P = .036) and HF education (P = .005) but not angiotensin-converting enzyme inhibitor/angiotensin receptor blocker, β-blocker, aldosterone antagonist, implantable cardioverter-defibrillator therapy, and anticoagulation for atrial fibrillation.

Conclusions Use of dedicated HF clinics varied in cardiology outpatient practices and was associated with greater use of cardiac resynchronization therapy and HF education but not other guideline-recommended therapies. (Am Heart J 2010;159:238-44.)

Heart failure (HF) is a chronic, progressive condition that imposes a significant burden on health care systems and patients. More than 5.7 million Americans have HF, and with 670,000 new cases per year, the number of patients adversely impacted by HF continues to grow.[1] Heart failure results in substantial morbidity and mortality and is among the most frequent causes of hospitalization. Furthermore, direct and indirect costs of treating HF are expected to reach $37.2 billion by the end of 2009.[1] Cost-effective strategies that improve delivery of evidence-based, guideline-recommended care known to improve clinical outcomes are essential to reduce the burden of HF on health care systems and patients.

In prior studies, clinical practice guidelines developed by national organizations were slowly and inconsistently

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RCT# NCT00303979.

Submitted October 16, 2009; accepted November 24, 2009.

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0002-8703/$ - see front matter

doi:10.1016/j.ahj.2009.11.022

applied in clinical practice, and certain evidence-based, guideline-driven HF therapies were significantly underused.[2-5] Some cardiology-based outpatient practices with disease management programs or dedicated HF clinics used significantly more guideline-recommended medication therapy than practices without such programs.[6,7] However, little is known about the effectiveness of a dedicated HF clinic on delivery of recommended HF therapies in outpatient cardiology settings. The objective of this study was to examine the influence of a dedicated HF clinic on delivery of guideline-recommended therapies for outpatients with HF in cardiology practices.

Methods

IMPROVE HF is a prospective, longitudinal cohort study designed to characterize current management of patients with chronic HF or postmyocardial infarction and left ventricular systolic dysfunction (LVSD) in outpatient cardiology practices (clinical trial registration with www.clinicaltrials.gov; identifier NCT00303979). The overall study objectives, design, and methods, including definitions of 7 process measures, were previously described.[5,8] Community-based cardiology practices with or without academic affiliation and university setting and with single-specialty or multispecialty services from all regions of the United States were invited to participate.[8] Chronicity of HF was assessed by physician documentation on at least 2 separate visits for HF treatment in the current practice setting during the 2-year period preceding study initiation. Evidence of LVSD was confirmed quantitatively by an LV ejection fraction ≤35% on the most recent echocardiogram, nuclear multiple-gated acquisition scan, contrast ventriculogram, or magnetic resonance imaging scan, or qualitatively by evidence of moderate to severe LVSD with stage C heart failure or postmyocardial infarction without HF (stage B). The IMPROVE HF registry and this study are sponsored by Medtronic Inc, Minneapolis, MN. The authors are solely responsible for the design and conduct of this study, all study analyses, the drafting and editing of the article, and its final contents.

Analyses were derived from baseline data entered into the IMPROVE HF registry between 2005 and 2007. Baseline data collected from medical chart reviews using a standardized case report form included patient demographic and clinical characteristics, medical history, previous cardiac-based treatments, New York Heart Association (NYHA) functional class, laboratory and diagnostic test results, and current pharmacologic and device-based HF treatments. Documented contraindications, intolerance, or other reasons (economic, social, religious, refusal, or nonadherence) for not prescribing evidence-based HF therapies were collected. The QRS duration was based on a computerized reading or physician measurement from the most recent electrocardiogram. A representative sample of patient medical records was screened to yield a median of 90 patients from each practice (25th and 75th percentiles, 58 and 107, respectively) for the baseline assessment period as described in the trial design report.[11]

Practice characteristics were collected by survey at baseline and included geographic location, practice type, number of cardiologists and electrophysiologists, affiliation with a hospital or transplant center, presence of a device-based clinic, annual average number of patients, number of HF-devoted advanced practice nurses or physician assistants (APN/PA), and presence or absence of a dedicated HF clinic. Analysis examining the effects of a dedicated HF clinic on delivery of guideline-recommended therapies for HF was prespecified in the study protocol.

All practices were approved by a local or central institutional review board or received institutional review board waivers. Highly trained chart review specialists collected data for eligible patients. Data quality was addressed by developing prespecified definitions for each variable (data dictionary), using consistent chart review specialists to collect data, and regular, centralized retraining and testing of specialists to maintain data abstraction accuracy. Average interrater reliability (κ) was 0.82. To further ensure completeness and accuracy of collected data, 1.7 automated quality checks per data field were performed and reported monthly. The registry coordinating center was Outcome Sciences Inc (Cambridge, MA).

Table I. IMPROVE HF quality improvement measures

ACC/AHA performance measures for outpatients with HF
Use of ACEI and/or ARB*
Use of β-blocker*
Use of anticoagulation therapy*
Documentation that education (all aspects: salt-restricted diet, monitoring weight daily, monitoring for signs of worsening HF, and activity/exercise recommendations) was provided to eligible patients
Other metrics of guideline-recommended HF therapy†
Use of aldosterone antagonist*
Use of an ICD‡ for eligible patients without documented contraindications
Use of CRT§ for eligible patients without documented contraindications

* For eligible patients without documented contraindications or intolerance.
† Not current ACC/AHA performance measures.
‡ Includes ICD and CRT with defibrillation.
§ Includes CRT with defibrillation and pacemaker.

Guideline-recommended HF therapies

Seven process of care measures (1 education and 6 therapies) were prospectively selected by the IMPROVE HF Steering Committee to quantify the quality of outpatient delivery of guideline-recommended therapies for HF (Table I).[8] All 7 measures were therapies designated as class 1 (useful and effective) in the American College of Cardiology/American Heart Association (ACC/AHA) guidelines.[9] The 7 measures were selected through a process that was independent of the study sponsor, described in the design and baseline findings reports,[5,8] and conformed to the methodology used for selection of national measures of cardiovascular care quality.[10] Of the 7 IMPROVE HF measures, 4 were ACC/AHA outpatient performance measures (Table I). Documentation of NYHA functional status was a prerequisite of eligibility for aldosterone antagonist, implantable cardioverter-defibrillator (ICD), and cardiac resynchronization therapy (CRT) measures; therefore, only patients with quantitative or qualitative documentation of NYHA functional status were included in these care measures analyses. Inclusion in care measure calculation included only patients who met defined criteria for each care measure and for whom there were no contraindications, intolerance, refusal, or other

documented rationale explaining why the guideline-recommended therapy should not be provided.[10]

Delivery of HF therapies by presence of a dedicated HF clinic

Presence or absence of a dedicated HF clinic was based on a yes/no response to the question, "Does the practice have a clinic dedicated to HF?" Outpatient, office, and hospital- or clinic-based HF disease management programs are multimodal in enrollment criteria, reimbursement, team versus single practitioner approach, use of multidisciplinary health care providers, and complexity of services; therefore, "dedicated HF clinic" was not predefined further. In addition, practices were asked to provide responses to 9 prespecified HF treatment components (patient education, clinical care pathways, medication compliance, home visits, dedicated nurse provider, remote patient monitoring for HF, telemonitoring, dedicated quality improvement program, and assessment of outcome data), and a blank field option was available to describe other components.

Statistical methods

Statistical analyses were performed by independent biostatisticians contracted by Outcome Sciences Inc. Descriptive statistics for patient and practice characteristics were calculated and reported for practices that completed a practice survey at baseline. The proportion and 95% CIs, or median and 25th and 75th interquartile percentages, for patient and practice characteristics and the 7 care measures were based on presence or absence of a dedicated HF clinic. Univariate general estimating equation (GEE) hierarchical models were first calculated for patient clinical and demographic characteristics and practice characteristics that might be associated with presence or absence of a dedicated HF clinic. The GEE analyses controlled for correlation of data within practices. Multivariate GEE models, based on variables that were statistically significant at 0.10 in the univariate GEE models, were then calculated to identify factors independently associated with presence of a dedicated HF clinic. Analyses were completed using SAS software, version 9.1 (SAS Institute, Cary, NC). Tests were 2-sided, and results were considered statistically significant at $P < .05$.

Table II. Baseline patient characteristics by presence of a dedicated HF clinic (n = 15,381)

Patient characteristic	Dedicated HF clinic: Yes (n = 7211)	Dedicated HF clinic: No (n = 8710)	P
Age, mean (SD), y	67.4 (13.6)	69.8 (12.8)	<.001
Male, %	70.9	71.1	.764
Race, %			<.001
White	40.1	42.5	
Black	11.3	7.2	
Not documented or missing	46.8	48.7	
HF etiology, ischemic, %	60.9	68.9	<.001
History			
Atrial fibrillation, %	30.9	30.7	.819
Diabetes, %	34.2	33.8	.550
Hypertension, %	60.1	63.0	<.001
Myocardial infarction, %	37.6	41.0	<.001
Chronic obstructive pulmonary disease, %	15.9	16.9	.088
Coronary artery bypass graft surgery, %	28.7	32.8	<.001
Peripheral vascular disease, %	10.8	11.8	.057
Depression, %	9.6	8.1	.001
LV ejection fraction, mean (SD), %	25.0 (7.2)	25.8 (6.9)	<.001
Systolic blood pressure, mean (SD), mm Hg	119.4 (19.2)	121.4 (18.6)	<.001
Diastolic blood pressure, mean (SD) mm Hg	70.0 (11.4)	70.7 (11.2)	<.001
Resting heart rate, mean (SD), beat/min	72.1 (11.7)	72.1 (11.5)	.808
Rales on most recent examination, %	4.0	3.4	<.001
Edema on most recent examination, %	20.1	19.4	.033
Sodium, mean (SD), mEq/L	139.2 (3.5)	139.2 (4.7)	.238
Blood urea nitrogen, mean (SD), mg/dL	25.9 (15.3)	25.7 (14.5)	.491
Creatinine level, mean (SD), mg/dL	1.4 (0.8)	1.4 (0.8)	.949
QRS duration, mean (SD), ms	131.1 (39.5)	127.2 (40.7)	<.001
NYHA functional class, %			<.001
I-II	64.8	74.7	
III-IV	35.2	25.3	

Results

Medical records of 15,381 patients receiving care at 167 outpatient cardiology practices were included in analysis. All 167 IMPROVE HF practices completed survey information, with 41.3% of practices indicating they had a dedicated HF clinic. Patients managed in a dedicated HF clinic were younger, more likely to be black and to have nonischemic heart disease, and were less likely to have common comorbid conditions (Table II). Patients receiving care in dedicated HF clinics had lower ejection fraction, lower blood pressure, longer QRS duration, higher rates of rales and edema, and worse functional status than patients not treated in dedicated HF clinics. Practices with dedicated HF clinics were more likely to be hospital based, associated with a university setting, and associated with a transplant center. Practices with dedicated HF clinics also had more cardiologists per practice, were more likely to use APN/PA, and more likely to be multispecialty practices compared with practices without dedicated HF clinics (Table III). Geographic location of practices, number of patients treated annually, and type of medical record documentation system were not associated with presence of dedicated HF clinics.

Of IMPROVE HF practices, 162 (97%) provided details about service components. Patient education (88.6%) and medication compliance assessment/counseling (82.0%) were widely prevalent, consistent with domains of a disease management model. Less prevalent service components were remote HF patient monitoring (43.1%), use of clinical care pathways and a dedicated nurse provider (both 33.5%), telemonitoring (32.5%), routine assessment of outcome data (19.8%), dedicated quality improvement program (13.2%), and home visits (7.8%).

Table III. Baseline practice characteristics by presence of a dedicated HF clinic (n = 167)

Practice characteristics	Dedicated HF clinic		
	Yes (n = 69)	No (n = 98)	*P*
Region, %			.381
South	30.4	44.9	
Northeast	36.2	29.6	
Central	17.4	14.3	
West	13.0	11.2	
Missing	2.9	0.0	
Practice setting, %			<.001
University-teaching	15.9	2.0	
Nonuniversity, teaching	27.5	17.3	
Nonuniversity, nonteaching	52.2	73.5	
Missing	4.4	7.2	
Hospital-based, %	40.6	18.4	<.001
Transplant center, %	20.3	2.0	<.001
Advanced practice nurse/physician assistant, %			<.001
0	10.1	49.0	
>0.5-1	37.7	23.5	
≥2	50.7	23.5	
Multispecialty practice, %	31.9	18.4	.033
Cardiologists, n, mean (SD)	14.8 (13.4)	10.1 (7.9)	<.001
Patients seen annually, n, mean (SD)	2750 (2973)	3572 (4584)	.566
Medical record system, %			.520
Electronic	31.9	32.7	
Paper only	42.0	44.9	
Mixed	21.7	14.3	
Missing	4.3	8.2	

Delivery of guideline-recommended HF therapies

Practices with dedicated HF clinics were more likely to provide care resulting in greater conformity to 3 of 7 guideline-recommended HF therapy measures studied: angiotensin-converting enzyme inhibitor/angiotensin receptor blocker (ACEI/ARB) (P = .019), β-blocker (P = .025), and HF education (P = .009) (Figure 1).

Table IV provides univariate GEE hierarchical analysis and adjusted multivariate odds ratios and CIs for use of the 7 guideline-recommended HF therapy measures associated with presence of a dedicated HF clinic. Multivariate analysis controlled for patient and practice characteristics. In univariate analyses, 5 of 7 measures (ACEI/ARB, β-blocker, aldosterone antagonist, ICD therapy, and HF education) were more likely in practices with dedicated HF clinics. After multivariate adjustment, HF education remained associated with presence of a dedicated HF clinic (P = .005) and CRT therapy became modestly significantly associated with presence of a dedicated HF clinic (P = .036).

Discussion

This study is among the first to assess the influence of a dedicated HF clinic on conformity to evidence-based, guideline-recommended HF therapies among patients with chronic systolic HF in outpatient cardiology practices. Presence of a dedicated HF clinic was associated with increased conformity to CRT therapy and documentation of HF education but not evidence-based HF drug therapies or use of ICD therapy, suggesting potential benefit of a dedicated HF clinic on a few guideline-recommended HF therapies. More important, these findings provide insight about current delivery of care to HF patients in outpatient cardiology practices and may provide rationale for nonpositive findings of reported trials of disease management programs in a variety of settings.[11-15] These findings may also prompt discussion of recommendations to improve the quality of care delivery for certain guideline-recommended HF therapies.

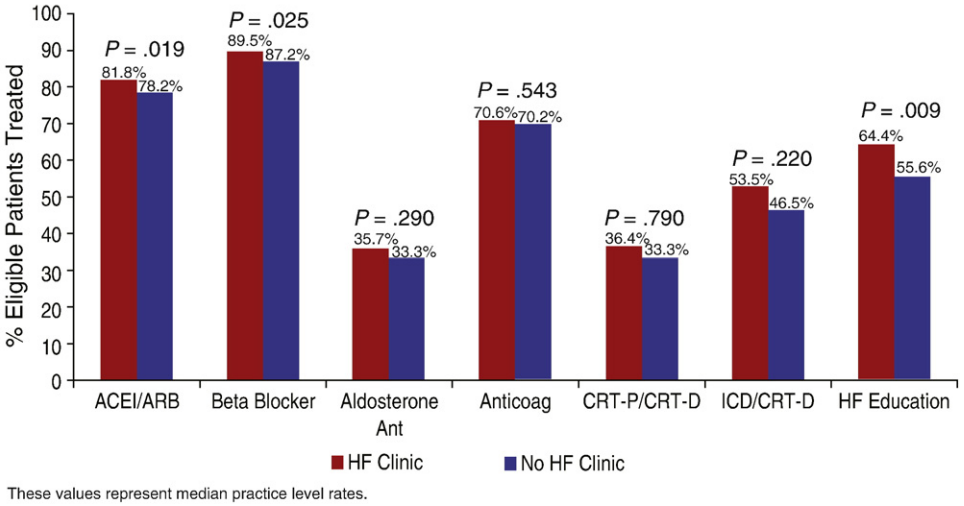
Dedicated HF clinics are classified as 1 of 3 forms of HF disease management programs (along with home care and telemonitoring) that have gained considerable attention since being developed in the 1980s.[16] Dedicated HF clinics have considerable heterogeneity in services associated with a wide range of goals, such as improving clinical outcomes, quality of life, and cost of care; identifying worsening health status to prevent hospitalization; assertively delivering medical management to achieve clinical stability; optimizing patient HF knowledge and self-care maintenance and management expectations to improve adherence to the plan of care; monitoring adherence to self-care to prevent volume overload and associated morbidity; and providing psychologic and socioeconomic care to minimize barriers of plan of care adherence.[17] Another elemental goal of disease management programs is to monitor and report quality of care and outcomes[17]; however, reports in the literature focus on clinical outcomes and not the degree of conformity of care, using carefully constructed performance measure definitions. Our findings reflect a need for dedicated HF clinics to engage in rigorous ongoing quality of care assessment and continuous cycles of monitoring to achieve conformity to evidence-based, guideline-recommended HF therapies.

Heterogeneity in outpatient HF clinic practices, including dedicated HF clinics, may be based on oversight policies and practices, comprehensiveness of services offered, use of APN/PA and other support personnel, reimbursement, patient and geographic characteristics, and use of electronic medical record systems. It is unknown if specific features of a contemporary multimodal HF clinic predict greater success in achieving conformity to evidence-based, guideline-recommended HF therapies. Thus, system and patient variables should be investigated to determine areas of focus for cardiology practices.

Documentation of HF education

It was not surprising that practices with dedicated HF clinics had higher rates of adherence to documentation of

Figure 1



Rates of guideline-recommended therapy measures by presence of a dedicated HF clinic. *Ant*, Antagonist; *Anticoag*, anticoagulation for atrial fibrillation; *CRT-P/CRT-D*, cardiac resynchronization therapy-pacemaker/-defibrillator.

Table IV. Unadjusted and adjusted odds ratio for adherence to guideline-recommended HF therapy measures in eligible patients by presence of a dedicated HF clinic

	Presence of dedicated HF clinics					
	Univariate			Multivariate		
HF therapy measure	Odds ratio (95% CI)	Wald χ^2	*P*	Odds ratio (95% CI)	Wald χ^2	*P*
ACEI/ARB	1.23 (1.13-1.33)	23.83	<.001	1.17 (0.68-2.00)	0.32	.571
β-Blocker	1.26 (1.14-1.39)	21.95	<.001	0.96 (0.55-1.67)	0.03	.874
Aldosterone antagonist	1.24 (1.05-1.47)	6.45	.011	0.77 (0.56-1.06)	2.51	.113
Anticoagulation	1.06 (0.93-1.20)	0.72	.395	1.11 (0.79-1.56)	0.34	.560
CRT-P/CRT-D	1.13 (0.90-1.42)	1.17	.279	1.47 (1.03-2.10)	4.38	.036
ICD/CRT-D	1.15 (1.04-1.26)	8.24	.004	0.97 (0.64-1.46)	0.02	.881
HF education	1.52 (1.43-1.63)	158.00	<.001	1.87 (1.22-2.89)	8.08	.005

Anticoagulation, Anticoagulation for atrial fibrillation; *CRT-P/CRT-D*, cardiac resynchronization therapy-pacemaker/-defibrillator.

HF education because provision of education was the most frequent service component identified (89% of practices). Importantly, disease management programs with clinical outcomes benefits had substantial education components that were systematically applied.[18,19]

Study findings add to evidence that a dedicated HF clinic is more likely to result in documentation of the provision of all components of HF education; however, literature that links medical record documentation of HF education with subsequent clinical outcomes is scarce. Using hospital medical record data, 1-year postdischarge survival was improved in patients receiving item-by-item HF core measures. For the education documentation component, the hazard ratio was 0.79.[20] In contrast, medical record documentation of hospital discharge education was not associated with lower death or rehospitalization rates in the first 60 to 90 days after discharge.[21] Thus, follow-up time might be an important variable in outcomes assessment.

In addition, depth in education content and consistent delivery by health care professionals was associated with improved outcomes. In 2 hospital-based studies, a substantive education intervention that included one-on-one, 1-hour HF education delivered by cardiac nurses decreased subsequent hospitalization compared with usual care.[22,23] In outpatient cardiology practices, focused education programs delivered by cardiac and noncardiac nurses led to improvement in a composite score of death or unplanned rehospitalization, number of hospitalizations, and total hospital days,[18] adherence to

HF self-care,[18,24,25] quality of life,[18] and knowledge.[24] In this study, consistency in education content delivery was not studied. Ultimately, uncertainty exists regarding the effect of education documentation on quality of HF care. Further research that addresses factors associated with education delivery and documentation, such as health literacy, patient understanding of education received, frequency of education, topics of focus, and depth of content discussed, is needed.

Use of CRT

In IMPROVE HF, a dedicated HF clinic was modestly associated with increased conformity to CRT therapy according to ACC/AHA guidelines, whereas ICD use did not differ by cardiology practices with or without a HF clinic. Rationale requires further study. This finding may reflect the views of some key opinion leaders in HF, in that there is general support for CRT in HF because it improves LV ejection fraction, functional status, hospitalization rate, and survival, but questions have been raised as to the magnitude of benefit and cost effectiveness of ICD devices.[26] Given that CRT is underused in eligible patients without contraindications[27] and disparities in use are common,[28] study findings may lend support for dedicated HF clinics as potential means to improve this component of evidence-based care. Future research should address the level of collaborative care in dedicated HF clinics and effects on clinical outcomes.

Heart failure and cardiac drug therapies

In this study, there was no independent association of dedicated HF clinics with delivery of ACEI/ARB, β-blocker, aldosterone antagonist, or warfarin drug therapy for eligible patients. Our findings challenge conventional beliefs and suggest that dedicated HF clinics may not favorably influence provision of guideline-recommended, evidence-based drug therapies compared with care in cardiology practices without dedicated HF clinics. The ACEI/ARB and β-blocker use rates were high at baseline (80% and 86%, respectively), and there was less variation in use between practices,[5] decreasing the likelihood that dedicated HF clinics could significantly increase rates. However, aldosterone antagonist and warfarin therapies were underused (36% and 69%, respectively) at baseline,[5] suggesting alternative explanations for findings. Cardiologists may set expectations for delivery of drug therapies in dedicated HF clinics or may initiate drug therapies before referral. There might be less initiative or approval (if care is delivered by APN/PA) to assertively add drug therapies in eligible patients, based on guideline recommendations. In relation to aldosterone antagonist and warfarin therapies, cardiology providers may be less knowledgeable about guideline-based eligibility criteria or may not want to deal with side effects or safety issues, laboratory monitoring expectations, or target dosages for specific agents. If the latter is rationale for poor use of guideline-recommended therapies, a dedicated HF clinic may be an ideal setting if standards of practice are consistently implemented and staff have the resources, knowledge, and experience to meet standards.

This study has several strengths. Detailed information on patient eligibility for all guideline-recommended therapies was collected, allowing restriction of data analysis to include only patients eligible for each therapy. Our study methodology adjusted for significant patient and practice characteristics in multivariate GEE analyses. To the best of our knowledge, this study represents the largest description of the association of dedicated outpatient cardiology HF clinics with use of evidence-based, guideline-recommended HF therapies in patients with chronic HF and eligibility for therapies.

Limitations

Several limitations were inherent in the IMPROVE HF design and should be considered when interpreting findings. Practice and patient characteristics were collected by a practice survey completed after study enrollment and medical chart review. Assessments were dependent on accuracy and completeness of documentation by practice staff and abstraction by data collectors. Conformity and eligibility for guideline-recommended therapy measures were based on medical record documentation. A proportion of patients reported to be eligible for treatment but not treated may have had contraindications or intolerances that were undocumented. Failure to document NYHA functional class and QRS duration precluded determination of eligibility for aldosterone antagonist, CRT, and ICD for the entire cohort. Residual measured and unmeasured confounding variables cannot be excluded and may account for some findings on multivariate analyses. For example, in practices with dedicated HF clinics, some patients may not have been treated in the dedicated HF clinic. Data on exposure to dedicated HF clinics at the patient level were not collected. The findings of this study may not apply to practices with different patient demographic and clinical characteristics or unusual variations in the defining characteristics of a dedicated HF clinic from practices enrolled in IMPROVE HF. Because all patients were observed in cardiology practices, bias of ascertainment may be related to this point of care. Finally, clinical outcomes based on dedicated HF clinic status were not collected and are an important topic for future study.

Conclusions

Outpatient cardiology practices vary significantly in their use of dedicated HF clinics. After controlling for patient and practice characteristics, dedicated HF clinics in outpatient cardiology practices were associated with higher rates of documentation of HF education and CRT

therapy use but not other guideline-recommended therapies. Further research is needed to determine if alternative structuring and staffing, greater individual patient exposure, and different disease management components or delivery methodologies are required for dedicated HF clinics to have greater impact on the use of guideline-recommended HF therapies.

Acknowledgement

Technical editorial support was provided by CommGeniX LLC, Tampa, FL, with payment by Medtronic Inc.

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