Equitable Improvement for Women and Men in the Use of Guideline-Recommended Therapies for Heart Failure: Findings From IMPROVE HF

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ABSTRACT

Background: Although sex-based disparities in use of guideline-recommended heart failure (HF) therapies have been described, little is known about whether performance improvement (PI) initiatives produce equitable improvements in guideline-recommended therapies.

Methods and Results: IMPROVE HF is a prospective study of a practice-based PI intervention in patients with systolic HF or post−myocardial infarction left ventricular dysfunction. Mean changes from baseline to 24 months after intervention were compared between women and men for treatment with angiotensin-converting enzyme inhibitors/angiotensin receptor blockers, β-blockers, aldosterone antagonists, anticoagulation for atrial fibrillation, cardiac resynchronization therapy (CRT), implantable cardioverter-defibrillator (ICD), and HF education. This analysis included 15,170 patients at 167 cardiology practices (4,383 [28.9%] women, 10,787 [71.1%] men). At baseline, women were less likely than men to be treated with anticoagulation and ICD. Significant improvements in 6 of 7 quality measures were evident at 24 months for both sexes. The absolute magnitude of improvement was similar for 5 measures and significantly better in women for CRT, ICD, and composite care.

Conclusions: This PI intervention was associated with similar or greater increases in use of guideline-recommended HF therapies for eligible women compared with men. Clinical decision support and performance feedback may help to ensure improved, equitable care for men and women with HF.

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Key Words: Quality of care, evidence-based medicine, performance measures, sex.

Heart failure (HF) is a chronic disease that results in >12 million outpatient office visits annually as well as substantial morbidity and mortality.[1] There are a number of evidence-based mortality-reducing therapies for HF, and national guidelines provide strong recommendations for use of these therapies for eligible patients.[2,3] The clinical trials that have demonstrated the impact of therapies on reductions in morbidity and mortality for patients with HF and left ventricular systolic dysfunction (LVSD) have for the most part enrolled many fewer women than men and did not stratify patient outcomes by sex. Retrospective studies and post hoc analyses have been performed to determine sex-specific benefits of

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medication and device therapies for HF. These analyses, with few exceptions, have demonstrated similar efficacy for men and women with HF.[4]

Despite compelling evidence from clinical trials and guidelines, sex-based disparities in use of HF therapies have been demonstrated in hospitalized patients treated for HF and for those receiving care as outpatients.[5−12] Several quality improvement initiatives have been associated with improvements in delivery of guideline-recommended therapies in patients with HF, but it is not known whether these initiatives produce similar improvements in care for women and for men with HF.[13−15] This investigation was undertaken to determine if an HF quality improvement initiative applied in outpatient practice settings would lead to similar improvements in use of guideline-recommended therapies in women and in men.

Methods

IMPROVE HF (Registry to Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting) is a prospective cohort study designed to characterize management of patients with diagnosed HF or previous myocardial infarction and LVSD in outpatient cardiology practices. The methods of IMPROVE HF and the overall study objectives have been described in detail elsewhere.[16,17] Community and university-affiliated single-specialty or multispecialty outpatient cardiology practices from all regions of the United States were invited to participate.[16] Eligible patients included those with a clinical diagnosis of HF with LVSD or previous myocardial infarction and LVSD documented by a cardiologist on ≥2 separate visits. LVSD was defined quantitatively as a left ventricular ejection fraction (LVEF) of ≤35% or qualitatively as moderate to severe LVSD demonstrated on the most recent echocardiogram, nuclear multiple-gated acquisition scan, contrast ventriculogram, or magnetic resonance imaging scan. Patients with preserved systolic function or without LV function measured were not eligible for inclusion in the cohort.

Patient demographic and clinical characteristics, including sex, medical history, previous treatments, laboratories, diagnostic tests, and current treatments for HF, were collected by medical chart abstraction before implementation of the performance improvement intervention. Documentation of reasons for not prescribing evidence-based HF therapies, including contraindications, intolerance, economic, social, and religious reasons, patient noncompliance, and patient refusal, was also collected. Race and ethnicity were abstracted if documented in the medical record. A representative sample of medical records was screened to yield an average of 90 eligible patients from each practice using the methodology previously described.[16] In brief, participating practices prepared electronic lists of patients from their medical billing system and/or electronic medical record. Patients included had ≥1 eligible International Classification of Disease, 9th Revision code, had ≥2 visits in the preceding 2 years, and were ≥18 years old. If possible, based on the capabilities of the medical billing system and/or electronic medical record, the records of patients without LV function measured, without documented LVSD, and who had expired were excluded at this stage. The patient list was then uploaded onto the study processing system, assigned an internal code, and sorted at random. The selected charts were then subjected to detailed review to verify patient eligibility for the study, and, if eligible, full chart abstraction was completed.

All practices participating in IMPROVE HF were approved by a local Institutional Review Board (IRB) or central IRB, or received IRB waivers. A total of 34 highly trained centralized chart review specialists underwent ongoing training and testing to maintain accuracy in data abstraction. Data elements and corresponding definitions were used and were consistent with American College of Cardiology/American Heart Association (ACC/AHA) HF data standards. The average interrater reliability was substantial ($\kappa = 0.82$). To further ensure data quality and completeness, 1.7 automated data quality checks were performed for each data field, and data quality reports were generated and reviewed monthly by project staff. In addition, 10% of participating sites were randomly selected for an audit of all patient data for 20% of the patients enrolled in IMPROVE HF. The mean data concordance rate with source documentation was 94.5% (range, 92.3%−96.3%). The registry coordinating center was Outcome Sciences (Cambridge, Massachusetts).

Guideline-Recommended Quality Metrics

Seven process measures were prospectively selected by the IMPROVE HF Steering Committee to evaluate the quality of HF care in outpatient cardiology practices.[16] These included angiotensin-converting enzyme inhibitors/angiotensin II receptor blockers (ACEI/ARB), β-blockers, aldosterone antagonists, anticoagulation for atrial fibrillation, cardiac resynchronization therapy with pacemaker/cardiac resynchronization therapy with defibrillator (CRT-P/CRT-D), implantable cardioverter-defibrillator/CRT-D (ICD/CRT-D), and HF education. Each of these measures is designated as class I (useful and effective) in the ACC/AHA HF guidelines.[2,3] The process by which the 7 quality measures were selected was independent of the study sponsor and described in greater detail in earlier publications.[16,17] Patients eligible for inclusion in an individual quality measure calculation included only those who met the criteria for a given therapy and for whom there were no contraindications, intolerance, or other documented reason to explain why the therapy was not provided.[16] Documentation of New York Heart Association (NYHA) functional class is required to be considered eligible for treatment with an ICD, CRT, or aldosterone antagonist. Therefore, only patients with quantitative or qualitative documentation of NYHA functional class at a level consistent with the measure specifications were included in analyses of these 3 quality measures.[17] Two summary measures of care were also calculated. The first was a total composite score, defined as the percentage of the total indicated quality measures provided to eligible patients, whereas the second was an all-or-none care measure, defined as the proportion of patients who received each quality measure for which they were eligible.[17,18]

Performance Improvement Intervention

An earlier publication provided the details of the IMPROVE HF process-of-care improvement intervention, which was developed to assist cardiology practices in improving treatment of patients with HF.[17] Intervention components included a guideline-based clinical decision support tool kit, educational materials, practice-specific data reports, benchmarked quality-of-care reports, and structured educational and collaborative opportunities.[17] The intervention also included evidence-based best practices algorithms, clinical pathways, standardized encounter forms, checklists, pocket cards, chart stickers, and patient education and other