

HFSA Position Statement

Implications of Recent Clinical Trials for Heart Failure Performance Measures

EXECUTIVE COUNCIL OF THE HEART FAILURE SOCIETY OF AMERICA¹

Background

Over the past five years the Centers for Medicare & Medicaid Services (CMS) and the Joint Commission for the Accreditation of Health Care Organizations (JCAHO) have striven to improve the quality of health care by promulgating indicators of quality care. These indicators, also known as performance measures, assess processes of care for several key conditions including heart failure (HF). Several criteria are applied during the definition of performance measures, but the first and perhaps most important criterion is that the measure reflects care for which there is consensus that a given procedure or treatment is useful and effective. Consensus, in turn, has been determined from guidelines published by recognized professional organizations. These indicators are growing in consequence as organizations are increasingly reporting them publicly, and some arrangements with purchasers are creating linkages between the quality indicators and bonus payments for services.

The use of ACE inhibitors in patients with HF and reduced left ventricular ejection fraction (LVEF) is a key performance measure. The support for this measure, however, has evolved significantly over the past several months in response to the publication of two clinical trials of angiotensin receptor blocker (ARB) use. This position statement will address the impact of these trial results on the formulation of performance measures for HF care.

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¹This statement was reviewed and approved by the HFSA Executive Council (Appendix 1). A single reprint is available by contacting the HFSA at 651-642-1633 or writing the HFSA, Court International Suite 240 South, 2550 University Avenue West, St. Paul, MN 55114.

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Recent Clinical Trials

The following two trials published in the last several months are particularly germane to this issue.

I. CHARM Program: A total of 7601 patients were enrolled in three separate randomized trials to either 32 mg candesartan or placebo in three distinct HF populations, and results were reported for each trial individually as well as for the total population. In patients with an LVEF $\leq 40\%$ who were intolerant of ACE inhibitors, candesartan reduced the primary end point of cardiovascular mortality plus HF hospitalization by 23% ($p = 0.0004$), a reduction driven principally by decreased hospitalizations. In HF patients with an LVEF $\leq 40\%$ who were already taking an ACE inhibitor and, many of them, also a beta blocker, CV mortality and HF hospitalizations were reduced by 15% ($p = 0.011$) compared with the use of an ACE inhibitor alone, though all-cause mortality was not reduced significantly. The third trial involved HF patients with LVEF $> 40\%$ and demonstrated no significant benefit, though the secondary endpoint of total HF hospitalizations was reduced significantly. For the primary endpoint of the overall analysis of all three trials, the effect of candesartan on all-cause mortality did not achieve statistical significance ($p = 0.055$).

II. VALIANT: This study compared the ARB valsartan with the ACE inhibitor captopril or a combination of the two in 14,808 patients who had reduced LVEF ($\leq 35\%$ by echocardiography or contrast ventriculography or $\leq 40\%$ by radionuclide ventriculography) or clinical or radiographic signs of HF within 10 days after an MI. There was no statistically significant difference in all cause mortality among the three treatments. The 95% confidence intervals around the mortality estimates were sufficiently small for it to be said that the ARB was not inferior to the ACE inhibitor.

Discussion

Guideline recommendations for HF will be driven by the following points: 1) the benefit of ACE inhibitors is firmly established; 2) the benefit of ARBs within HF is established among patients who are ACE inhibitor intolerant; 3) ARBs

appear “non-inferior” to ACE inhibitors post-MI. These points will result in a distinction between recommendations for ACE inhibitors and ARBs, with the guidelines favoring the former as first line therapy.

Guidelines, however, are not performance measures and the distinction is important. Performance measures currently do not give partial credit for a particular clinical strategy. Thus, currently if patients are not treated with an ACE inhibitor and do not have documentation of a contraindication to an ACE inhibitor then they are given no credit by the quality indicator, whether or not they are taking an ARB. Although the Guidelines endorse ACE inhibitors more enthusiastically than ARBs, the evidence regarding the non-inferiority of ARBs to ACE inhibitors suggests that the indicator be made more permissive and count ARBs as an acceptable alternative to ACE inhibitors for patients with heart failure and reduced LVEF. The benefit of ARBs is now sufficiently established, and the differential value between the 2 classes of agents is small, at most. The counting of patients receiving ARBs as satisfying a performance measure for medical therapy in HF is a reasonable approach. Given that there remain many patients with HF and reduced LVEF who are not on either an ACE inhibitor or an ARB, it is important to send a clear message of the necessity for treatment with either of these medications. The Guideline recommendations that ACE inhibitors should be considered the first line therapy remains the policy of this organization,

but this statement recommends that physicians receive credit for using one of these agents in the appropriate setting. Moreover, for patients who are ACE inhibitor intolerant, due to cough or related symptoms, ARBs should definitely be used.

Recommendation

Performance measures should assess the proportion of patients with HF and reduced LVEF who are treated with either ACE inhibitors or ARBs. For patients intolerant to ACE inhibitor due to cough or related symptoms, ARBs should definitely be offered to the patient as an alternative therapy.

Appendix 1

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