
BACKGROUND: Despite therapy with diuretics, ACE inhibitors and digoxin morbidity and mortality in heart failure remain high and might respond favorably to an additional vasodilator.

METHODS AND RESULTS: Male patients (n=450) with chronic heart failure (cardiac dysfunction and impaired exercise performance) on optimal current therapy (97% enalapril, 89% diuretics) were randomly assigned to double-blind treatment with felodipine extended release (5 mg BID) or placebo for 3 to 39 months (average, 18 months). Felodipine significantly reduced blood pressure and, at 3 months, increased ejection fraction (2.1% versus -0.1% units in the placebo group, P=.001) and reduced plasma atrial natriuretic peptide levels (-2.9 versus 26.9 pg/mL in the placebo group, P=.01) but did not improve exercise tolerance, quality of life, or the need for hospitalization. During long-term follow-up, the favorable effects on ejection fraction and atrial peptide did not persist, but felodipine prevented worsening exercise tolerance and quality of life. In the felodipine and placebo groups, mortality (13.8% versus 12.8%, respectively) and hospitalization (43% versus 42%) rates were similar, and a higher incidence of peripheral edema was the only apparent side effect of felodipine therapy.

CONCLUSIONS: Felodipine exerts a well-tolerated additional sustained vasodilator effect in patients with heart failure treated with enalapril, but the only possible long-term benefit was a trend for better exercise tolerance and less depression of quality of life in the second year of treatment. The drug appears to be safe but not clearly efficacious in patients with heart failure.