

To evaluate the effects of vasodilator therapy on mortality among patients with chronic congestive heart failure, we randomly assigned 642 men with impaired cardiac function and reduced exercise tolerance who were taking digoxin and a diuretic to receive additional double-blind treatment with placebo, prazosin (20 mg per day), or the combination of hydralazine (300 mg per day) and isosorbide dinitrate (160 mg per day). Follow-up averaged 2.3 years (range, 6 months to 5.7 years). Mortality over the entire follow-up period was lower in the group that received hydralazine and isosorbide dinitrate than in the placebo group. This difference was of borderline statistical significance. For mortality by two years, a major end point specified in the protocol, the risk reduction among patients treated with both hydralazine and isosorbide dinitrate was 34 percent (P less than 0.028). The cumulative mortality rates at two years were 25.6 percent in the hydralazine--isosorbide dinitrate group and 34.3 percent in the placebo group; at three years, the mortality rate was 36.2 percent versus 46.9 percent. The mortality-risk reduction in the group treated with hydralazine and isosorbide dinitrate was 36 percent by three years. The mortality in the prazosin group was similar to that in the placebo group. Left ventricular ejection fraction (measured sequentially) rose significantly at eight weeks and at one year in the group treated with hydralazine and isosorbide dinitrate but not in the placebo or prazosin groups. Our data suggest that the addition of hydralazine and isosorbide dinitrate to the therapeutic regimen of digoxin and diuretics in patients with chronic congestive heart failure can have a favorable effect on left ventricular function and mortality.