Additive effects of diltiazem and lisinopril in the treatment of elderly patients with mild-to-moderate hypertension.

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摘要

Abstract

A multicenter, double-blind, placebo-controlled trial with multifactorial design was conducted to evaluate the safety and efficacy of the calcium-channel blocker diltiazem, in a sustained release preparation, and the angiotensin converting enzyme inhibitor, lisinopril, in the treatment of elderly Chinese patients with mild-to-moderate hypertension. In addition to the hypotensive effects of combinations of both drugs compared with monotherapy, all given once daily, the effect on quality of life was also evaluated. This study consisted of a 3 x 2 multifactorial design in which 156 women and men with a sitting diastolic pressure of between 95 mm Hg and 114 mm Hg, after a 4-week placebo washout phase, were randomized to one of six treatment groups for 12 weeks of active treatment. Monotherapy with diltiazem 120 or 240 mg produced increasing reductions of systolic and diastolic blood pressure. Compared with placebo, lisinopril 10 mg had an effect intermediate between the diltiazem doses. The combinations of diltiazem 240 mg + lisinopril 10 mg and diltiazem 120 mg + lisinopril 10 mg showed increased efficacy in reducing systolic and diastolic blood pressure compared to these drug doses used in monotherapy, but the effect of the combinations was less than predicted by an additive model. Although the total number of other adverse events reported was similar for all active treatment groups compared to placebo, lisinopril-induced cough was common with an incidence of 31% after rechallenge. Premature drug withdrawal was necessary in four of 78 patients receiving lisinopril, due to intractable cough. The combination of diltiazem 240 mg and lisinopril 10 mg was significantly more effective at reducing blood pressure than either drug alone; this additive effect did not result in a higher rate of adverse effects or impairment of quality of life. Thus, combination therapy with these agents was well tolerated and resulted in increased efficacy in these elderly patients.