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Low-dose colchicine for secondary prevention of cardiovascular disease

A Randomized Controlled Trial

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Abstract

Objectives:

The objective of this study was to determine whether colchicine 0.5 mg/day can reduce the risk of cardiovascular events in patients with clinically stable coronary disease.

Background:

The presence of activated neutrophils in culprit atherosclerotic plaques of patients with unstable coronary disease raises the possibility that inhibition of neutrophil function with colchicine may reduce the risk of plaque instability and thereby improve clinical outcomes in patients with stable coronary disease.

Methods:

In a clinical trial with a prospective, randomized, observer-blinded endpoint design, 532 patients with stable coronary disease receiving aspirin and/or clopidogrel (93%) and statins (95%) were randomly assigned colchicine 0.5 mg/day or no colchicine and followed for a median of 3 years. The primary outcome was the composite incidence of acute coronary syndrome, out-of-hospital cardiac arrest, or

noncardioembolic ischemic stroke. The primary analysis was by intention-to-treat.

Results:

The primary outcome occurred in 15 of 282 patients (5.3%) who received colchicine and 40 of 250 patients (16.0%) assigned no colchicine (hazard ratio: 0.33; 95% confidence interval [CI] 0.18 to 0.59; $p < 0.001$; number needed to treat: 11). In a pre-specified secondary on-treatment analysis that excluded 32 patients (11%) assigned to colchicine who withdrew within 30 days due to intestinal intolerance and a further 7 patients (2%) who did not start treatment, the primary outcome occurred in 4.5% versus 16.0% (hazard ratio: 0.29; 95% CI: 0.15 to 0.56; $p < 0.001$).

Conclusions:

Colchicine 0.5 mg/day administered in addition to statins and other standard secondary prevention therapies appeared effective for the prevention of cardiovascular events in patients with stable coronary disease.

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