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The Effect of an EDTA-based Chelation Regimen on Patients With Diabetes Mellitus and Prior Myocardial Infarction in the Trial to Assess Chelation Therapy (TACT)

Authors

Abstract

Background—The Trial to Assess Chelation Therapy (TACT) showed clinical benefit of an EDTA-based infusion regimen in patients aged ≥ 50 years with prior myocardial infarction. Diabetes mellitus before enrollment was a prespecified subgroup.

Methods and Results—Patients received 40 infusions of EDTA chelation or placebo. A total of 633 (37%) patients had diabetes mellitus (322 EDTA and 311 placebo). EDTA reduced the primary end point (death, reinfarction, stroke, coronary revascularization, or hospitalization for angina; 25% versus 38%; hazard ratio, 0.59; 95% confidence interval [CI], 0.44–0.79; $P < 0.001$) for over 5 years. The result remained significant after Bonferroni adjustment for multiple subgroups (99.4% CI, 0.39–0.88; adjusted $P = 0.002$). All-cause mortality was reduced by EDTA chelation (10% versus 16%; hazard ratio, 0.57; 95% CI, 0.36–0.88; $P = 0.011$), as was the secondary end point (cardiovascular death, reinfarction, or stroke; 11% versus 17%; hazard ratio, 0.60; 95% CI, 0.39–0.91; $P = 0.017$). However, after adjusting for multiple subgroups, those results were no longer significant. The number needed to treat to reduce 1 primary end point over 5 years was 6.5 (95% CI, 4.4–12.7). There was no reduction in events in non–diabetes mellitus ($n = 1075$; $P = 0.877$), resulting in a treatment by diabetes mellitus interaction ($P = 0.004$).

Conclusions—Post–myocardial infarction patients with diabetes mellitus aged ≥ 50 demonstrated a marked reduction in cardiovascular events with EDTA chelation. These findings support efforts to replicate these findings and define the mechanisms of benefit. However, they do not constitute sufficient evidence to indicate the routine use of chelation therapy for all post–myocardial infarction patients with diabetes mellitus.

Clinical Trial Registration—URL: <http://www.clinicaltrials.gov>. Unique identifier: [NCT00044213](https://clinicaltrials.gov/ct2/show/study/NCT00044213).

Key Words: [diabetes mellitus](#) [myocardial infarction](#) [secondary prevention](#)

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