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Antioxidant therapy does not reduce pain in patients with chronic pancreatitis: the ANTICIPATE study

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Abstract

Background & aims: We investigated whether antioxidant therapy reduces pain and improves quality of life in patients with chronic pancreatitis.

Methods: We performed a double-blind, randomized, controlled trial that compared the effects of antioxidant therapy with placebo in 70 patients with chronic pancreatitis. Patients provided 1 month of baseline data and were followed for 6 months while receiving either antioxidant therapy (Antox version 1.2, Pharma Nord, Morpeth, UK) or matched placebo (2 tablets, 3 times/day). The primary analysis was baseline-adjusted change in pain score at 6 months, assessed by an 11-point numeric rating scale. Secondary analyses included alternative assessments of clinical and diary pain scores, scores on quality-of-life tests (the European Organization for Research and Treatment of Cancer [EORTC-QLQ-C30], Quality of Life Questionnaire-Pancreatic modification [QLQ-PAN28], European Quality of Life questionnaire [EuroQOL EQ-5D], and European Quality of Life questionnaire - Visual Analog Score [EQ-VAS]), levels of antioxidants, use of opiates, and adverse events. Analyses, reported by intention to treat, were prospectively defined by protocol.

Results: After 6 months, pain scores reported to the clinic were reduced by 1.97 from baseline in the placebo group and by 2.33 in the antioxidant group but were similar between groups (-0.36; 95% confidence interval [CI], -1.44 to 0.72; P = .509). Average daily pain scores from diaries were also similar (3.05 for the placebo group and 2.93 for the antioxidant group, a difference of 0.11; 95% CI, 1.05-0.82; P = .808). Measures of quality of life were similar between groups, as was opiate use and number of hospital admissions and outpatient visits. Blood levels of vitamin C and E, β -carotene, and selenium were increased significantly in the antioxidant group.

Conclusions: Administration of antioxidants to patients with painful chronic pancreatitis of predominantly alcoholic origin does not reduce pain or improve quality of life, despite causing a sustained increase in blood levels of antioxidants.

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