**Concomitant therapy with Cineole (Eucalyptole) reduces exacerbations in COPD: A placebo-controlled double-blind trial**

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Abstract Background: The clinical effects of mucolytics in patients with chronic obstructive pulmonary disease (COPD) are discussed controversially. Cineole is the main constituent of eucalyptus oil and mainly used in inflammatory airway diseases as a mucolytic agent. We hypothesised that its known mucolytic, bronchodilating and anti-inflammatory effects as concomitant therapy would reduce the exacerbation rate and show benefits on pulmonary function tests as well as quality of life in patients with COPD. Methods: In this double-blind, placebo-controlled multi-center-study we randomly assigned 242 patients with stable COPD to receive 200 mg of cineole or placebo 3 times daily as concomitant therapy for 6 months during winter-time. The frequency, duration and severity of exacerbations were combined as primary outcome measures for testing as multiple criteria. Secondary outcome measures included changes of lung function, respiratory symptoms and quality of life as well as the single parameters of the exacerbations. Results: Baseline demographics, lung function and standard medication of both groups were comparable. During the treatment period of 6 months the multiple criteria frequency, severity and duration of exacerbations were significantly lower in the group treated with cineole in comparison to placebo. Secondary outcome measures validated these findings. Improvement of lung function, dyspnea and quality of life as multiple criteria were statistically significant relative to placebo. Adverse events were comparable in both groups. Conclusion: Concomitant therapy with cineole reduces exacerbations as well as dyspnea and improves lung function and health status. This study further suggests cineole as an active controller of airway inflammation in COPD by intervening in the pathophysiology of airway inflammation of the mucus membrane.