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Title: Effects of ghrelin on the dyspnea pattern in cachectic COPD: Exploratory analysis of a substudy of a multicenter, randomized, double-blind, placebo-controlled trial of ghrelin treatment

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Body: Background: The substudy of the ghrelin treatment, multicenter, randomized, double-blind, placebo-controlled trial demonstrated that ghrelin administration was associated with improved exertional capacity and improvements in ventilatory-cardiac parameters in cachectic COPD patients. To clarify more precisely the dyspnea pattern during exercise, the data from the substudy were analyzed in an exploratory manner. Method: Of 20 cachectic COPD patients who were randomized to pulmonary rehabilitation with intravenous ghrelin (2 mg/kg, n = 10) or placebo (n = 10) twice daily for 3 weeks in the substudy, 17 patients (ghrelin = 9, placebo = 7) could be investigated for the dyspnea break-point on the dyspnea-ratio (%) of delta oxygen uptake (Vo_2) (= peak minus resting Vo_2) curve. Results: No treatment effect compared with placebo was found in the Borg scale at the dyspnea break-point, or in the plasma lactate level at the lactate break-point. However, a significant treatment effect by ghrelin administration in the percentage of delta Vo_2 at the dyspnea break-point (treatment effect -18%, 95% CI -35.9 to -0.0; p = 0.049) was obtained. Similarly, the percentage of delta Vo_2 at the lactate break-point was significantly shifted to the early exercise phase compared with placebo (treatment effect -19%, 95% CI -34.1 to -4.2; p = 0.017). Conclusions: Cachectic patients with COPD benefited from ghrelin treatment in terms of shifts to the early exercise phase in the dyspnea break-point and in the lactate threshold during a standardized exercise program. Trial Registration: UMIN, number C000000061.