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Title: Nighttime symptoms and reduced quality of life among COPD patients

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Body: INTRODUCTION: Little is known about the impact of COPD symptoms at night on patients' quality of life. METHODS: In a 12-week, Phase III trial of twice-daily aclidinium (ACCORD I), COPD patients completed an electronic diary each morning for 2 weeks before baseline. Diaries included questions on presence and severity of nighttime symptoms and sleep quality. Health status and dyspnea were assessed via SGRQ and BDI. Post hoc analyses were performed to study the relationship between nighttime COPD symptoms and other symptomatic and health status measures. Nighttime symptoms were defined 2 ways: 1) ≥3 nights sleep disturbance during baseline week and 2) ≥3 nights coughing, wheezing, and/or breathlessness during baseline week. Data from the week before baseline for patients with >3 days of diary entries were analyzed via T-test and Chi-square. RESULTS: The analyses included 535 of 561 randomized patients. Patients with nighttime symptoms had significantly worse health status, as seen in SGRQ Total and domain scores, vs patients without (p<0.0001 for all, both definitions). A significantly higher percentage of patients with nighttime symptoms reported sleep disturbance on SGRQ vs those without (p<0.0001 both definitions). Patients with nighttime symptoms were more breathless (BDI domains, focal scores p<0.002, both definitions), had longer time to sleep onset, lower sleep quality, more awakenings, difficulty falling back to sleep, less total sleep, and were less rested in the AM (all p<0.02, both definitions) vs those with no symptoms. CONCLUSIONS: COPD nighttime symptoms are associated with impaired health status, breathlessness, and poor sleep. Clinicians should consider COPD nighttime symptoms when prescribing treatment.