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Title: Observational study to characterise 24-hour COPD symptoms: Interim analysis of ASSESS

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**Body:** Background: Little is known about the 24-hour profile of COPD symptoms. Aim: To assess the prevalence/severity of 24-hour COPD symptoms and their impact on patients' well-being. Methods: This ongoing, 6-month prospective observational study will recruit 720 patients with COPD. Baseline night-time, early-morning and day-time symptoms, HRQoL, anxiety/depression and sleep quality were assessed. A priori interim analysis: 11 Oct 2012. Results: 314 patients recruited to date: 69% male, mean±SD age 67±9 yrs, mean±SD % pred FEV<sub>1</sub> 49.7±17.8%. Baseline COPD symptom frequency/severity are reported in Table; in the week prior to baseline, 56% patients had symptoms throughout the day. Breathlessness was most common (67% patients); its prevalence increased during the day (28% night, 43% morning, 62% day). Patients with symptoms in 3 parts of the day had the worst HRQoL (CAT score 19.3 vs 6.7–16.8 in patients with symptoms in ≤2 parts of the day). Patients with any symptoms at night had higher anxiety/depression levels vs those with only morning and/or day symptoms or no symptoms (Hospital Anxiety and Depression Scale score 13.8–16.0 vs 8.3–12.4) and worse sleep quality (COPD and Asthma Sleep Impact Scale scores 33.7–48.7 vs 27.7–32.2).

Patients (%) with COPD symptoms\*

	Night	Morning	Day
Prevalence (any symptom)			
≥3 times past week	43	57	57
≥3 times typical week	48	62	61
Patients with ≥1 symptom	62	77	79
Severity (past week)			
No symptoms	48	25	22
Mild/moderate	45	65	68
Severe/very severe	6	9	9

<sup>\*</sup>to nearest %

Conclusions: Over half of patients had symptoms during the whole 24 hours; these patients had the worst HRQoL. Patients with night symptoms had poorest sleep quality and increased anxiety/depression.