Symptoms and impact of COPD assessed by a handheld electronic diary

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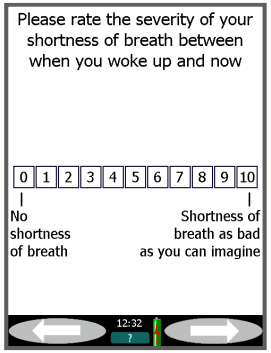
The symptoms of COPD frequently affect both patients' ability to function normally and their quality of life. When assessing symptoms of COPD using Patient-reported Outcomes (PRO) it is important to assess the impact of symptoms as well as their severity and frequency. We report data using PRO data collection with a handheld electronic diary (eDiary).



The eDiary was completed daily on awakening by a subset of 209 patients in a Phase III clinical trial of COPD. Patients were aged 44-86 years (mean 65.3, S.D. 8.7), and 140 (67.0%) were male. The eDiary included five individual symptoms of COPD, and questions on the bother and difficulty caused by COPD symptoms. All items were scored on a 0-10 numeric scale. Two morning assessments (since awakening; since last assessment) and one evening assessment were made each day.

Data are presented for the baseline (pre-treatment) period of the study. In each case the mean score of the last seven days before treatment started was analysed.

All symptoms in the eDiary were reported frequently (≥70% of baseline entries showing symptom present). Table 1 shows correlations between symptoms and bother (B) and difficulty (D) caused by COPD symptoms. Three assessment points are shown, M1: Morning Diary, Symptoms Since Waking; M2: Morning Diary, Symptoms Since Last Assessment; and E: Evening Diary. Correlations for shortness of breath were very high, in all cases >0.95. For other symptoms, correlations were lower, but still substantial (0.64 –0.86).

Table 1. Correlations (Person's r) between individual symptoms and overall Bother/Difficulty caused by COPD symptoms.

	Assessment Point				
	M1	M2		E	
Symptom	B	B	D	B	D
Shortness of Breath	0.957	0.956	0.953	0.958	0.958
Phlegm/ Mucus	0.763	0.718	0.688	0.675	0.661
Chest Tightness	0.856	0.861	0.858	0.844	0.849
Wheezing	0.798	0.782	0.761	0.722	0.706
Coughing	0.733	0.688	0.639	0.656	0.644

Regression modelling showed that shortness of breath was a highly significant ($p<0.0001$) predictor of bother and difficulty. Other symptoms added little predictive power once shortness of breath had been taken into account.

Exploratory factor analysis gave a single factor comprising all eDiary items, including symptoms, bother and difficulty. Table 2 shows the factor loadings at the three assessment points. These were highest for shortness of breath, bother and difficulty.

The internal consistency of the eDiary was evaluated using Cronbach's alpha. This was very high with alpha being > 0.95 at all assessment points.

Table 2. Factor loadings for the single factor Identified by Exploratory Factor Analysis.

	Assessment Point		
Item	M1	M2	E
Shortness of Breath	0.942	0.947	0.944
Phlegm/ Mucus	0.90	0.853	0.839
Chest Tightness	0.921	0.922	0.913
Wheezing	0.900	0.885	0.845
Coughing	0.865	0.824	0.812
Bother	0.942	0.952	0.944
Difficulty	--	0.939	0.942

These results show that

1. The eDiary scale is unidimensional, and impact items (bother and difficulty) showed no tendency to dissociate from the symptom items. Thus a simple mean of all seven items can be used as a summary measure for the eDiary

2. Shortness of breath showed particularly high correlations with the impact items, This shows the key importance and relevance of shortness of breath to patients with COPD.

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