Evaluation of an electronic daily diary for measuring morning symptoms in Chronic Obstructive Pulmonary Disease

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Morning symptoms in Chronic Obstructive Pulmonary Disease (COPD) are a substantial burden to patients. Currently, there is no validated diary available addressing morning core symptoms specifically. A daily electronic diary (eDiary) has been developed on the basis of patient interviews to asses severity and bother caused by symptoms since awakening.

Please rate the severity of your shortness of breath between when you woke up and now

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

No shortness of breath — Shortness of breath as bad as you can imagine

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 study treatment period was 26 weeks, with 14 days of pre-treatment diary assessment. Diary scores were taken as the mean of each 7-day period during the study, using the last 7 days of the pre-treatment period as the baseline value. At the end of each week, patients competed a diary item in the evening recording change since the start of the study. Clinic assessments were carried out at baseline and at weeks 12 and 26, including the St George Respiratory Questionnaire (SGRQ) and Forced Expiratory Volume in 1 second (FEV1)

Compliance, assessed as percentage of scheduled entries completed, was 94% at the beginning of the study and 81.3% at the end.

All symptoms in the eDiary occurred frequently, the incidence ranging from 62% - 78% (Figure)
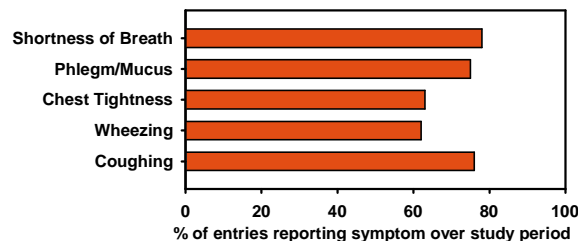
Exploratory factor analysis, using mean scores over the last 7 days of the baseline (pre-treatment) period, showed a single factor. All items had strong loadings onto the factor, the highest being those for shortness of breath and bother (Table). This indicates that the mean of the six items of the eDiary may be used as a summary measure (Overall Mean, OM). The table also shows the correlations of each of the symptom scores with the bother item. The strongest correlation is that with shortness of breath, which is very high.

Item	Factor Loading	Correlation with bother
Shortness of Breath	**0.94**	**0.96**
Phlegm/Mucus	**0.90**	**0.76**
Chest Tightness	**0.92**	**0.86**
Wheeze	**0.90**	**0.8.0**
Coughing	**0.87**	**0.73**
Bothered by symptoms	**0.94**	**- -**

Test-retest reliability was assessed in 44 patients who reported no change in their condition between the baseline and week 1 assessments. In each case the mean over 7 days was taken. ICC was 0.96 for the OM, and > 0.94 for all individual items.

Concurrent validity was assessed using the correlations between eDiary scores a clinic-based patient-reported measure, the St George's respiratory questionnaire (SGRQ). The table shows correlations at baseline between eDiary scores and two subscales of the SGRQ.

The prediction was that correlations would be higher between bother and SGRQ impacts, and between symptom mean and SGRQ symptoms than for other pairs (highlighted). This was confirmed, but the differences are small, which may be due to the high inter-correlations of the eDiary items

eDiary Measure	SGRQ Subscale	
	Symptoms	**Impacts**
OM (6 items mean)	**0.54**	**0.56**
Symptom mean (5 items)	**0.56**	**0.52**
Bothered by Symptoms	**0.52**	**0.59**

Responsiveness was assessed in terms of change between baseline and week 26 for patients rated as (1) improved on **both** patient global assessments and FEV1 (increase $\geq$ 120mL) or (2) uncertain/no change. Effect sizes were –0.75 and –0.12 respectively, both improvements.

These results show that the Early Morning Symptom eDiary is valid, reliable, and responsive to change.

Shortness of breath is a key symptom, and correlates very strongly with the bother experienced by patients due to COPD.

The single factor found in the factor analysis supports the use of the overall mean score as a summary measure.

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