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Early View

Research letter

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The use of online visual analogue scales in idiopathic pulmonary fibrosis

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Take-home message: The visual analogue scale is a valid and reliable tool to assess symptoms over time in IPF. Because of their simplicity, visual analogue scales have the potential to be used for systematic evaluation of disease course in trials and daily practice.

Key words: interstitial lung disease, patient-reported outcomes, home monitoring, quality of life, symptoms

Word count: 1198 words

Introduction

Idiopathic pulmonary fibrosis (IPF) is a progressive, deadly disease with a major impact on the lives of patients[1]. Symptom burden and quality of life (QoL) can be assessed with patient-reported outcome measures (PROMs). In the past decade, PROM use was increasingly advocated to capture the impact of treatments and interventions on patients' symptoms and wellbeing[2]. PROMS are often lengthy, on paper, and with difficult scoring systems, hampering direct use in clinical practice[2]. Thus, there is a need for easy-to-use PROMs in IPF and other ILDs, both for clinical trials and daily practice.

A visual analogue scale (VAS) is a simple instrument to assess symptoms, and has been validated in a wide range of chronic diseases[3, 4]. So far, studies using VAS in ILD are scarce. One study that evaluated VAS scores at two different time points indicated that VAS can reliably detect changes in dyspnea and fatigue in patients with ILD over time[5]. Previously, we have shown that online administration of PROMs is feasible in elderly patients with IPF, and allows for frequent evaluation of disease course at a low burden for patients and healthcare providers[6, 7].

In this study, we aimed to evaluate the validity and reliability of weekly online VAS in patients with IPF.

Methods

Patients completed VAS using an online application, as part of a 24-week multicenter randomized controlled trial on home monitoring[7]. Adults with a diagnosis of IPF, according to the ATS/ERS/JRS/ALAT guidelines, about to start on anti-fibrotic medication, were eligible to participate[1]. This study was approved by the Medical Ethical Committee of the four participating centers. Patients provided written informed consent before study entry. During study visits at baseline, 12, and 24 weeks patients performed pulmonary function testing and completed Kings Brief Interstitial lung disease questionnaire (K-BILD), EQ-5D-5L, and global rating of change (GRoC)[8-10]. Patients randomized into the home monitoring group completed weekly VAS scores; patients in the standard care group completed VAS scores at baseline, 12, and 24 weeks. All PROMS were completed using a secured application (Curavista, Gezondheidsmeter, the Netherlands) on a tablet computer. After completion of PROMs, patients were provided with a graphical overview of their results over time.

This study included VAS on dyspnea (VASD), fatigue (VASF), cough (VASC), and general wellbeing (VASG) on a continuous scale with numeric markings from 0-10 and description at both ends, with a recall period of one week. For VASD, VASF, and VASC a higher score indicates worse symptoms; for VASG a higher score indicates a better general wellbeing. The K-BILD is a 15-item questionnaire on health-related quality of life in ILD with a recall period of two weeks, divided in three domains (breathlessness and activities, psychological, and chest symptoms). The EQ-5D-5L consists of five items on overall health-related quality of life, and a VAS on general wellbeing, with a recall period of one day. The GRoC evaluates overall change in health status compared to the previous assessment, from -7 (very much worse) to +7 (much better). Stable disease was defined as a GRoC score between -2 and +2[10]. Pearson correlation was used to calculate correlations between PROMs and lung function parameters at all timepoints. Reliability over time was assessed using the intraclass correlation coefficient (ICC) for weekly measurements during the first 12 weeks using a mixed model, in patients with stable disease.

Results

90 patients were included in the study, of whom 83 completed PROMs. Mean age was 71 years (SD 6.9), 91% was male. 46 patients were assigned to the home monitoring group, of whom 41 completed weekly VAS scores.

VASF, VASD, and VASG had a moderate to strong significant correlation with K-BILD total and breathlessness domain score at all timepoints (table 1). VASC had a weak to moderate significant correlation with K-BILD scores. Correlations between VAS scores and EQ-5D-5L scores were slightly lower. As shown in table 1, most correlations between VAS scores and other PROMs seemed to become stronger over time. No relevant correlations were found between VAS scores and forced vital capacity (FVC). Diffusion capacity of the lung for carbon monoxide (DLCO) weakly correlated with VAS scores.

Based on GRoC score, 29 of 41 patients in the weekly VAS group had stable disease during the first 12 weeks of the study. In these patients, the ICC for weekly measurements was high for VASF (0.84) and VASD (0.76), and moderate for VASG (0.65) and VASC (0.63). Similar results were found when comparing

	Week	**VAS Dyspnea**	*p-value*	**VAS Fatigue**	*p-value*	**VAS Cough**	*p-value*	**VAS General wellbeing**	*p-value*
K-BILD Total score	0	-0.59	*<0.001*	-0.61	*<0.001*	-0.25	*0.02*	0.46	*<0.001*
	12	-0.58	*<0.001*	-0.65	*<0.001*	-0.31	*0.004*	0.59	*<0.001*
	24	-0.71	*<0.001*	-0.62	*<0.001*	-0.50	*<0.001*	0.60	*<0.001*
K-BILD Breathlessness score	0	-0.66	*<0.001*	-0.58	*<0.001*	-0.22	*0.04*	0.43	*<0.001*
	12	-0.60	*<0.001*	-0.68	*<0.001*	-0.28	*0.01*	0.59	*<0.001*
	24	-0.71	*<0.001*	-0.61	*<0.001*	-0.50	*<0.001*	0.63	*<0.001*
EQ-5D-5L Index score	0	-0.48	*<0.001*	-0.48	*<0.001*	-0.03	*0.81*	0.24	*0.03*
	12	-0.27	*0.01*	-0.35	*0.01*	-0.13	*0.24*	0.29	*0.008*
	24	-0.55	*<0.001*	-0.54	*<0.001*	-0.30	*0.007*	0.46	*<0.001*
EQ-5D-5L VAS score	0	-0.42	*<0.001*	-0.39	*<0.001*	-0.17	*0.13*	0.25	*0.02*
	12	-0.55	*<0.001*	-0.50	*<0.001*	-0.36	*0.01*	0.33	*0.003*
	24	-0.71	*<0.001*	-0.62	*<0.001*	-0.48	*<0.001*	0.55	*<0.001*
FVC (%)	0	-0.06	*0.58*	-0.10	*0.36*	-0.01	*0.91*	0.09	*0.41*
	12	-0.32	*0.003*	-0.36	*0.001*	-0.18	*0.10*	0.27	*0.01*
	24	-0.21	*0.06*	-0.23	*0.05*	-0.23	*0.005*	0.42	*<0.001*
DLCO (%)	0	-0.40	*<0.001*	-0.35	*0.002*	-0.28	*0.01*	0.18	*0.12*
	12	-0.30	*0.02*	-0.37	*0.003*	-0.25	*0.04*	0.20	*0.12*
	24	-0.34	*0.004*	-0.28	*0.02*	-0.29	*0.01*	0.35	*0.002*

VAS data of week 0 and week 12: VASF (0.85), VASD (0.73), VASG (0.62) and VASC (0.60).

Table 1. Correlation coefficient (r) of VAS scores with K-BILD, EQ-5D-5L and lung function parameters (n=83) . K-BILD = King's Brief Interstitial Lung disease questionnaire, VAS = visual analogue scale, FVC = forced vital capacity, DLCOc = diffusion capacity of the lung for carbon monoxide

Discussion

Our results indicate that the visual analogue scale is a valid and reliable instrument to assess symptoms over time in patients with IPF. VAS scores correlated well with validated PROMs, especially the ILD-specific K-BILD questionnaire. Moreover, ICCs for weekly VAS measurements were acceptable to good.

As the K-BILD questionnaire reflects health-related QoL specific for ILD, the correlation between VAS scores and K-BILD was stronger than with the generic EQ-5D-questionnaire. These results were in line with a previous study by Yates et al, who additionally showed that change in VAS scores over time correlated with change in K-BILD scores [5]. Remarkably, VAS cough had a weaker association with K-BILD scores, likely because no cough-related questions are included in the K-BILD. However, previous studies in IPF found that VAS cough correlated well with change in objective cough measurements, and with cough-specific HRQoL questionnaires such as the Leicester Cough Questionnaire [11, 12]. None of the VAS scores correlated well with lung function parameters, which is consistent with previous studies in IPF, emphasizing the additive value of PROMs next to physiological parameters[13].

Interestingly, fatigue and dyspnea were the most stable symptoms with a high test-retest reliability over time (ICC >0.70). ICCs for cough and general wellbeing were slightly lower, indicating more variability over time. The VAS on general wellbeing was measured with the question: 'how did you feel the last week'? Non-disease related factors may also influence the answer to this question, potentially explaining the greater variability found.

Online VAS scores can be easily measured at a low burden for patients. Furthermore, they require less cognitive skills, making them particularly useful for broad implementation. In the online application, patients and care providers were provided with a graphical overview of symptom severity over time, which may help to improve insights in disease course[6, 7]. Whether frequent online completion of VAS also facilitates early identification of disease progression or acute exacerbations in ILD should be subject for future studies. A randomized trial in patients after lung cancer treatment showed that weekly online symptom monitoring was associated with better survival compared to standard surveillance[14]. An additional advantage of visual analogue scales is that they are easier to translate than longer questionnaires, and likely less sensitive to cultural influences.

Generally, questionnaires are administered with 3 to 6-month intervals, but with a short recall period of ≤2 weeks[5]. More granular VAS data may guide decisions on optimal recall periods for PROMs. Moreover, the minimal clinically important difference (MCID) for different VAS needs to be established, as the current study was not designed for this purpose. One single-center study estimated the MCID for VAS dyspnea and fatigue in a more heterogeneous group of patients with ILD, but their results need to be confirmed and validated in larger cohorts[5]. To do so, we propose to include VAS as exploratory endpoint in clinical trials.

A limitation of this study is the lack of a VAS on emotional wellbeing or depression. As emotional wellbeing is a complex construct with often multiple determinants, partly unrelated to the disease, it can be questioned if this can be meaningfully captured by a one item VAS. Recently a 5-item VAS has been validated to screen for psychiatric symptoms, which may be a tool for further exploration in ILD[15].

In conclusion, VAS scores significantly correlate with validated PROMs in IPF and are reproducible over time. Because of their simplicity, visual analogue scales have the potential to be used for systematic evaluation of disease course in trials and daily practice.

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