

The use of online visual analogue scales in idiopathic pulmonary fibrosis

Copyright ©The authors 2022.

This version is distributed under the terms of the Creative Commons Attribution Non-Commercial Licence 4.0. For commercial reproduction rights and permissions contact permissions@ersnet.org

This article has an editorial commentary: https://doi.org/10.1183/13993003.02312-2021

Received: 30 May 2021 Accepted: 13 July 2021 To the Editor:

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 interstitial lung diseases (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 dyspnoea 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.

Patients completed VAS using an online application, as part of a 24-week multicentre randomised controlled trial on home monitoring [7]. Adults with a diagnosis of IPF, according to the American Thoracic Society/European Respiratory Society/Japanese Respiratory Society/Latin American Thoracic Society 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 centres. Patients provided written informed consent before study entry. During study visits at baseline, 12, and 24 weeks, patients performed pulmonary function testing and completed the King's Brief Interstitial Lung Disease questionnaire (K-BILD), EQ-5D-5L, and global rating of change (GRoC) [8–10]. Patients randomised 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 dyspnoea (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 1 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 2 weeks, divided into 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 1 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.







Shareable abstract (@ERSpublications)

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. https://bit.ly/3BuxJsf

Cite this article as: Moor CC, Mostard RLM, Grutters JC, et al. The use of online visual analogue scales in idiopathic pulmonary fibrosis. Eur Respir J 2022; 59: 2101531 [DOI: 10.1183/13993003.01531-2021].

90 patients were included in the study, of whom 83 completed PROMs. Mean \pm so age was 71 ± 6.9 years, 91% were 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 time points (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. Diffusion capacity of the lung for carbon monoxide 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 data from week 0 and week 12 for VASF (0.85), VASD (0.73), VASG (0.62) and VASC (0.60).

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.* [5], who additionally showed that change in VAS scores over time correlated with change in K-BILD scores. 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 health-related QoL questionnaires such as the Leicester Cough Questionnaire [11, 12]. None

	\\\\ C \.		140 C 11		\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\		1400	
	VAS dyspnoea	p-value	VAS fatigue	p-value	VAS cough	p-value	VAS general wellbeing	p-value
K-BILD total score								
Week 0	-0.59	< 0.001	-0.61	< 0.001	-0.25	0.02	0.46	< 0.001
Week 12	-0.58	< 0.001	-0.65	< 0.001	-0.31	0.004	0.59	< 0.001
Week 24	-0.71	< 0.001	-0.62	< 0.001	-0.50	< 0.001	0.60	< 0.001
K-BILD breathlessness score								
Week 0	-0.66	< 0.001	-0.58	< 0.001	-0.22	0.04	0.43	< 0.001
Week 12	-0.60	< 0.001	-0.68	< 0.001	-0.28	0.01	0.59	< 0.001
Week 24	-0.71	< 0.001	-0.61	< 0.001	-0.50	<0.001	0.63	< 0.001
EQ-5D-5L index score								
Week 0	-0.48	< 0.001	-0.48	< 0.001	-0.03	0.81	0.24	0.03
Week 12	-0.27	0.01	-0.35	0.01	-0.13	0.24	0.29	0.008
Week 24	-0.55	< 0.001	-0.54	< 0.001	-0.30	0.007	0.46	< 0.001
EQ-5D-5L VAS score								
Week 0	-0.42	< 0.001	-0.39	< 0.001	-0.17	0.13	0.25	0.02
Week 12	-0.55	< 0.001	-0.50	< 0.001	-0.36	0.01	0.33	0.003
Week 24	-0.71	< 0.001	-0.62	< 0.001	-0.48	<0.001	0.55	< 0.001
FVC (%)								
Week 0	-0.06	0.58	-0.10	0.36	-0.01	0.91	0.09	0.41
Week 12	-0.32	0.003	-0.36	0.001	-0.18	0.10	0.27	0.01
Week 24	-0.21	0.06	-0.23	0.05	-0.23	0.005	0.42	< 0.001
D _{LCO} (%)								
Week 0	-0.40	<0.001	-0.35	0.002	-0.28	0.01	0.18	0.12
Week 12	-0.30	0.02	-0.37	0.003	-0.25	0.04	0.20	0.12
Week 24	-0.34	0.004	-0.28	0.02	-0.29	0.01	0.35	0.002

of the VAS scores correlated well with lung function parameters, which is consistent with previous studies in IPF, emphasising the additive value of PROMs alongside physiological parameters [13].

Interestingly, fatigue and dyspnoea 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 randomised 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-centre study estimated the MCID for VAS dyspnoea 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.

Catharina C. Moor¹, Remy L.M. Mostard², Jan C. Grutters^{3,4}, Paul Bresser⁵ and Marlies S. Wijsenbeek¹

¹Dept of Respiratory Medicine, Interstitial Lung Diseases Centre of Excellence, Erasmus Medical Center, Rotterdam, The Netherlands. ²Dept of Respiratory Medicine, Zuyderland Medical Center, Heerlen, The Netherlands. ³Interstitial Lung Diseases Centre of Excellence, Dept of Pulmonology, St Antonius Hospital, Nieuwegein, The Netherlands. ⁴Division of Heart and Lungs, University Medical Center Utrecht, Utrecht, The Netherlands. ⁵Dept of Respiratory Medicine, OLVG, Amsterdam, The Netherlands.

Corresponding author: Marlies S. Wijsenbeek (m.wijsenbeek-lourens@erasmusmc.nl)

Conflict of interest: C.C. Moor reports grants and lecture payments from Boehringer Ingelheim, outside the submitted work. R.L.M. Mostard reports personal fees from Boehringer Ingelheim, Roche and Galapagos, outside the submitted work. J.C. Grutters has nothing to disclose. P. Bresser has nothing to disclose. M.S. Wijsenbeek reports grant payments to institution from the Netherlands Organization for Health Research and Development during the conduct of the study; grant, contract payments, consulting fees, lecture payments and advisory board payments to institution from Boehringer Ingelheim, Hoffman la Roche, The Netherlands Organisation for Health Research and Development, The Dutch Lung Foundation, The Dutch Pulmonary Fibrosis Patient Association, The Thorax Foundation, ErasmusMC, Sarcoidosis.nl, Galapagos, Bristol Myers Squibb, Galecto, Respivant, Novartis, Savara; support for attending meetings from Boehringer Ingelheim and Hoffman la Roche, outside the submitted work; and holds the following unpaid leadership roles: secretary of the Idiopathic Interstitial Pneumonia group of the European Respiratory Society, member of the board of the Netherlands Respiratory Society, member of the

scientific advisory board of the European Idiopathic Pulmonary Fibrosis and Related Disorders Federation, chair of the educational committee of the European Reference Network for Rare Lung Diseases, advisory board of the Dutch Lungfibrosis and Sarcoidosis patient associations.

Support statement: This work was supported by the Netherlands Organization for Health Research and Development (grant: 848016002). Funding information for this article has been deposited with the Crossref Funder Registry.

References

- 1 Raghu G, Remy-Jardin M, Myers JL, et al. Diagnosis of idiopathic pulmonary fibrosis. An official ATS/ERS/JRS/ ALAT clinical practice guideline. Am J Respir Crit Care Med 2018; 198: e44–e68.
- 2 Kalluri M, Luppi F, Vancheri A, *et al.* Patient-reported outcomes and patient-reported outcome measures in interstitial lung disease: where to go from here? *Eur Respir Rev* 2021; 30: 210026.
- 3 Rhee H, Belyea M, Mammen J. Visual analogue scale (VAS) as a monitoring tool for daily changes in asthma symptoms in adolescents: a prospective study. *Allergy Asthma Clin Immunol* 2017; 13: 24.
- 4 Ries AL. Minimally clinically important difference for the UCSD Shortness of Breath Questionnaire, Borg Scale, and Visual Analog Scale. *COPD* 2005; 2: 105–110.
- 5 Yates H, Adamali HI, Maskell N, et al. Visual analogue scales for interstitial lung disease: a prospective validation study. QJM 2018; 111: 531–539.
- 6 Moor CC, van Manen MJG, Tak NC, *et al.* Development and feasibility of an eHealth tool for idiopathic pulmonary fibrosis. *Eur Respir J* 2018; 51: 1702508.
- Moor CC, Mostard RLM, Grutters JC, et al. Home monitoring in patients with idiopathic pulmonary fibrosis: a randomized controlled trial. Am J Respir Crit Care Med 2020; 202: 393–401.
- 8 Patel AS, Siegert RJ, Brignall K, et al. The development and validation of the King's Brief Interstitial Lung Disease (K-BILD) health status questionnaire. *Thorax* 2012; 67: 804–810.
- 9 Brooks R. EuroQol: the current state of play. Health Policy 1996; 37: 53–72.
- 10 Kamper SJ, Maher CG, Mackay G. Global rating of change scales: a review of strengths and weaknesses and considerations for design. *J Man Manip Ther* 2009; 17: 163–170.
- 11 Birring SS, Wijsenbeek MS, Agrawal S, et al. A novel formulation of inhaled sodium cromoglicate (PA101) in idiopathic pulmonary fibrosis and chronic cough: a randomised, double-blind, proof-of-concept, phase 2 trial. Lancet Respir Med 2017; 5: 806–815.
- 12 van Manen MJG, Birring SS, Vancheri C, *et al.* Effect of pirfenidone on cough in patients with idiopathic pulmonary fibrosis. *Eur Respir J* 2017; 50: 1701157.
- Kalluri M, Claveria F, Ainsley E, et al. Beyond idiopathic pulmonary fibrosis diagnosis: multidisciplinary care with an early integrated palliative approach is associated with a decrease in acute care utilization and hospital deaths. *J Pain Symptom Manage* 2018; 55: 420–426.
- 14 Denis F, Basch E, Septans AL, et al. Two-year survival comparing web-based symptom monitoring vs routine surveillance following treatment for lung cancer. JAMA 2019; 321: 306–307.
- Sirianni CD, Abeare CA, Ali S, et al. The V-5 provides quick, accurate and cross-culturally valid measures of psychiatric symptoms. Psychiatry Res 2021; 298: 113651.