King's Brief Interstitial Lung Disease (K-BILD) questionnaire: content relevance in progressive fibrosing ILD (PF-ILD)

Surinder S. Birring,¹ Donald M. Bushnell,² Katelyn Cutts,² Michael Baldwin,³ Klaus B. Rohr,³ Natalia Male³

¹King's College Hospital NHS Foundation Trust, London, UK; ²Evidera, Bethesda, MD, USA; ³Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany

BACKGROUND

- K-BILD is a patient-reported outcome questionnaire used to assess breathlessness and activities, psychological effects and chest symptoms in ILD
- The use of K-BILD has not been validated in patients with progressive fibrosing ILD

AIM: To assess the relevance and comprehension of the K-BILD questionnaire in patients with progressive fibrosing ILD



INCLUSION/EXCLUSION CRITERIA

- Diagnosis of progressive fibrosing ILD within 24 months of screening
- o Relative decline in FVC ≥10% predicted
- Relative decline in FVC ≥5-<10% predicted and either worsened respiratory symptoms or increased extent of fibrosis on HRCT
- Worsened respiratory symptoms and increased extent of fibrosis

- Patients with IPF
- were excluded
- Patients with pre-existing confounding medical
- conditions were excluded

STUDY DESIGN

- A qualitative study involving one-on-one interviews with adult patients with progressive fibrosing ILD
- All interviews were audio-recorded, and audio transcripts were analysed qualitatively using ATLAS.ti software (version 8.0)

Part One

Concept elicitation – interview about frequency and severity of the patient's symptoms

K-BILD¹



■ Three domains: breathlessness and activities, psychological and chest symptoms

Part Two

- 1. Completion of the K-BILD questionnaire
- 2. Debrief interview about the patient's understanding and interpretation of items, content validity and the recall period

Patient characteristics

Item no.

2

3

4 5

6

7

8

9

10

11

12

13

14

15



- 20 patients with progressive fibrosing ILD from
- USA (15)
- Germany (5)



Mean time since ILD diagnosis, based on imaging: 4.3 years (median 3.0; range 1.8-12.5)

RESULTS

K-BILD questionnaire

K-BILD item

I have been short of breath climbing stairs or walking up an incline or hill

Because of my lung condition, my chest has felt tight

Have you worried about the seriousness of your lung symptoms? Have you avoided doing things that make you short of breath?

Have you felt in control of your lung condition?

Have your lung symptoms made you feel annoyed or down?

I have felt the urge to inhale deeply and frequently (known as "air hunger")

My lung condition has made me feel anxious

How often have you experienced "wheezing" or whistling sounds from your chest?

How much of the time have you felt your lung disease is getting worse?

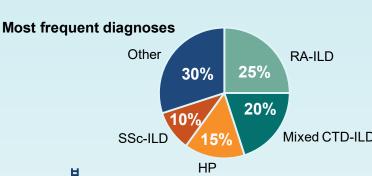
Has your lung condition interfered with your job or other daily tasks?

Have you expected your lung symptoms to get worse?

How much has your lung condition limited you carrying things (e.g. groceries)?

Has your lung condition made you think more about the end of your life?

Are you financially worse off because of your lung condition?





- Median FVC% predicted: 66.5%
- Median DL_{CO}% predicted: 53.0%

CONCEPTUAL ELICITATION

When patients discussed symptoms associated with their progressive fibrosing ILD:



100% discussed

95% discussed cough

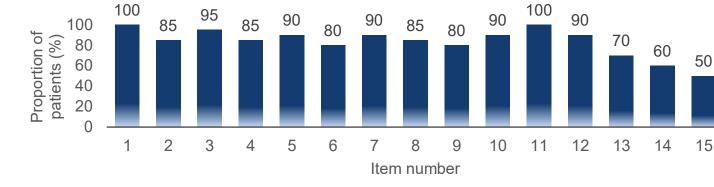
90% described fatigue

80% reported effects on physical functioning

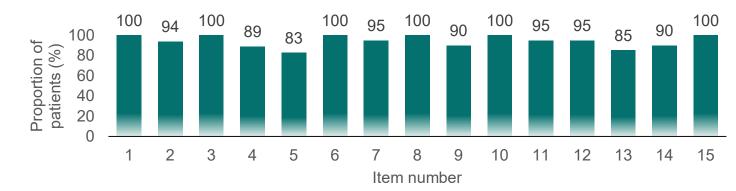
COGNITIVE DEBRIEFING

After completing the K-BILD, patients were interviewed on the content

Proportion of responding patients affected by K-BILD item (%)



Proportion of responding patients understanding K-BILD item (%)



TIME PERIOD

Most participants reported thinking of the past 2 weeks when completing the K-BILD (n=14/20)



All participants reported people would be able to recall the previous 2 weeks (n=19/19)

CONCLUSIONS

- K-BILD was easy to understand and relevant to patients with progressive fibrosina ILD
- Further studies should evaluate its validity and minimal clinically important difference for disease stability and progression



\ |---





Assesses a time period of 2 weeks

Each item is scored using a 7-point Likert scale



1. Patel AS, et al. Thorax 2012; 67,804-810.

■ Domains and total score ranges are 0–100, with a score of 100 representing best health status

Abbreviations

CTD-ILD, connective tissue disease-associated ILD; DLco, diffusing capacity of the lungs for carbon monoxide; FVC, forced vital capacity; HP, hypersensitivity pneumonitis; HRCT, high-resolution computed tomography; ILD, interstitial lung disease; IPF, idiopathic pulmonary fibrosis K-BILD, King's Brief Interstitial Lung Disease; RA-ILD, rheumatoid arthritis-associated ILD; SSc-ILD, systemic sclerosis-associated ILD.

Author disclosures

SSB has received consultancy fees from Boehringer Ingelheim. DMB and KC are paid employees of Evidera PPD and have also received research grants from Boehringer Ingelheim. MB, KBR and NM are paid employees of Boehringer Ingelheir

Acknowledgements

This analysis was supported by Boehringer Ingelheim International GmbH (BI). The authors meet criteria for authorship as ecommended by the International Committee of Medical Journal Editors (ICMJE). The authors did not receive payment for the development of the poster. Medical writing, editorial support and formatting assistance was provided by Darren Chow, of MediTech Media, UK, which was contracted and funded by Bl. Bl was given the opportunity to review the poster for medical and scientific accuracy as well as intellectual property considera

