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The King's Brief Interstitial Lung Disease (KBILD) questionnaire: an updated minimal clinically important difference

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ABSTRACT

Introduction The King's Brief Interstitial Lung Disease (KBILD) is a 15-item validated health-related quality of life (HRQOL) questionnaire. The method of scoring the KBILD has recently changed to incorporate a logit-scale transformation from one that used raw item responses, as this is potentially a more linear scale. The aim of this study was to re-evaluate the KBILD minimal clinically important difference (MCID) using the new logit -transformed scoring.

Methods 57 patients with interstitial lung disease (17 idiopathic pulmonary fibrosis, IPF) were asked to complete the KBILD questionnaire on two occasions in outpatient clinics. At the second visit, patients also completed a 15-item global rating of change of health status questionnaire (GRCQ). The MCID was calculated as the mean of four different methods: the change in KBILD for patients indicating a small change in GRCQ, patients with a 7%–12% change in FVC, 1 SE of measurement of baseline KBILD and effect size (ES) of 0.3.

Results The mean (SD) KBILD total score for all patients was 55.3 (15.6). 16 patients underwent a therapeutic intervention. 36 patients reported a change in their condition on the GRCQ; 22 deteriorated, 14 improved and 21 were unchanged. There was a significant change in KBILD total score in patients reporting a change in GRCQ; mean (SD) 57.0 (13.6) versus 50.0 (9.7); mean difference 7.0; 95% CI of difference 3.0 to 11.0; p<0.01. The change in KBILD total score correlated with the GRCQ scale; r=−0.49, p<0.01. The mean KBILD total score MCID was 5. The MCID of KBILD domains were 6 for Psychological, 7 for Breathlessness and Activities, and 11 for Chest Symptoms.

Conclusion The KBILD is a responsive tool for longitudinal assessment of HRQOL in patients with ILD. The MCID of the KBILD total score is a 5-unit change.

Key messages

- The King's Brief Interstitial Lung Disease (KBILD), an interstitial lung disease–specific health status questionnaire, has been recently updated to include a logit transformation step in its scoring, but its minimal clinically important difference (MCID) is not known.
- The MCID for the KBILD total score is 5 units.
- The logit-transformed KBILD questionnaire is a responsive scale and potentially more linear; the revised MCID will aid the clinical interpretation of health status scores.

INTRODUCTION

The King's Brief Interstitial Lung Disease (KBILD) questionnaire is a brief, valid, self-completed health status measure for interstitial lung disease (ILD).[1] We have previously reported the minimal clinically important difference (MCID) to be eight units.[2] MCID is defined as 'the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's (healthcare) management', and it helps the clinician interpret health status data.[3] The scoring system of the KBILD questionnaire has recently been modified by implementing logit transformation of raw item response scores. There has been no change to the number of items or construct of the questionnaire. Logit scores have the advantage of being more sensitive at the extreme spectrums of health-related quality of life (HRQOL) questionnaires as they are potentially more linear.[4] The KBILD logit scores correlate highly with raw scores (r=0.94–0.99, p<0.05).[5] We have recently reported KBILD logit scores to have good reliability and internal consistency, comparable with original KBILD raw scores.[5]

Logit scores, compared with raw scores, are numerically smaller at the extreme ends of HRQOL questionnaires. Therefore, we hypothesised that the MCID for KBILD logit scores will be less than 8. The aim of this paper was, therefore, to determine the new

MCID for KBILD logit scores. This is important because there are numerous clinical trials using the KBILD logit score version.[6–8]

METHODS

Subjects

The subjects were recruited in a previous study investigating the KBILD MCID using raw scores. Briefly, consecutive patients with ILD were recruited prospectively from secondary care (King's College Hospital) and tertiary care (Royal Brompton Hospital) specialist clinics. Clinical characteristics, comorbidities and medications were recorded using a structured questionnaire.

Questionnaires

King's Brief Interstitial Lung Disease Questionnaire

The KBILD is a self-completed health status questionnaire that comprises 15 items and a seven-point Likert response scale.[1] It has three domains: psychological, breathlessness and activities and chest symptoms. The KBILD domain and total score ranges are 0–100; 100 represents best health status.

Global Rating of Change questionnaire (GRCQ)

The GRCQ is a 15-point scale used to determine the MCID.[9] Patients score the change in their respiratory health status between clinic visits. The response scale ranges from 7 (a great deal worse) to −7 (a great deal better). All subjects were asked to complete four GRCQs, one for each KBILD domain and overall health status. The score for each GRCQ was classified as unchanged (scores 1, 0, 1), a small change (3, 2, 2, 3), a moderate change (5, 4, 4, 5) or large change (7, 6, 6, 7).

Minimal clinically important difference of KBILD

The recommended approach to estimating the MCID is to use numerous 'anchor-based' methods with a mixture of objective and subjective clinical indicators, and to use distribution-based estimates as supportive estimates.[10] The MCID should be representative of all these measures. For the FVC anchor, subjects were categorised as per Swigris *et al*,[11] 'unchanged' if the change in FVC (%) between visits was 0%–7%, 'minimal change' if 7%–12% and 'more than minimal change' if greater than 12%. The MCID using the GRCQ anchor was defined as the change in KBILD health status corresponding to a small change in GRCQ score. Two distribution-based methods were used to estimate the MCID: SE of measurement (SEM) and 0.3 effect size.[10 12] The calculation of these has been mentioned in our previous paper.[2]

Protocol

All patients completed the KBILD questionnaire at the first and second clinic visits (the latter being more than 4 weeks after the former). FVC was assessed according to American Thoracic Society standards at both visits.[13] Patients also completed the GRCQ at the second visit.

Analysis

SPSS software V.18 and RUMM 2030 (RUMM Laboratory) were used for statistical analysis. Mean and SD were used to describe parametric data. The KBILD raw scores from a previous study,[2] were converted to logit scores using Rasch analysis (RUMM software). The logit scores were transformed into a more easily understood scale (0–100) using an algorithm y=m+(s×logit score), where s=(wanted range)/(current range) and m=(wanted minimum)−(current minimum×s). This transformation was done in Microsoft Excel. The GRCQ score was expressed as an absolute number, that is, when the change was negative, the sign was reversed as was the sign of the corresponding change in KBILD score between visits.[3 9] Correlations were assessed with Pearson's (r) or Spearman's (rho) coefficient for parametric or non-parametric data. Paired

Table 1 Patient demographics

	All patients
N	57
Mean age, years (SD)	62 (11)
Women, %	67
Ethnicity, %	
Caucasian	75
Afro-Caribbean	9
South Asian	12
Other	4
Smoking status, %	
Current	2
Ex	36
Never	62
Mean time since diagnosis, years (SD)	4.0 (4.4)
FVC, % predicted (SD)	80 (25)
TLCO, % predicted (SD)	46 (18)
Immunosuppressant medications, %	
None	18
Prednisolone	37
Prednisolone+other	41
Other	4
KBILD Psychological	65 (25)
KBILD Breathlessness and Activities	46 (28)
KBILD Chest Symptoms	71 (26)
KBILD Total	62 (23)

All data are mean (SD) unless otherwise stated. South Asian patients originating from India, Pakistan or Bangladesh.
KBILD, King's Brief Interstitial Lung Disease Questionnaire; TLCO, transfer factor of the lung for carbon monoxide as % predicted.

Table 2 Minimal clinically important difference of KBILD (logit scores version)

	MCID anchor				
	GRCQ	FVC 7%–12%	1 SEM	ES 0.3	Mean MCID (range)
KBILD Psychological	5.3 (17.8)	7.4 (5.6)	5.8	5.8	6 (5–7)
KBILD Breathlessness and Activities	8.3 (18.3)	6.9 (12.0)	6.9	6.1	7 (6–8)
KBILD Chest	11.2 (19.4)	13.7 (21.5)	12.3	7.1	11 (7–14)
KBILD Total	6.7 (13.2)	6.1 (7.0)	3.8	4.7	5 (4–7)

All data are mean (SD) (apart from mean MCID (range)). Positive and negative changes in each GRCQ and FVC category are grouped together.
ES, effect size; GRCQ, Global Rating of Change Questionnaire; KBILD, King's Brief Interstitial Lung Disease Questionnaire; MCID, minimal clinically important difference; SEM, standard error of baseline measurement.

t-tests were used for group comparisons. P value <0.05 was considered significant.

RESULTS

Subject characteristics

Fifty-seven patients with ILD were recruited (17 patients with idiopathic pulmonary fibrosis, 18 with connective tissue disease ILD, 9 with idiopathic non-specific interstitial pneumonia, 8 with hypersensitivity pneumonitis, 4 with idiopathic organising pneumonia, 1 with lymphoid interstitial pneumonia). Demographics and baseline characteristics are shown in table 1. The mean duration between visits was 9 months. Sixteen patients underwent a therapeutic trial for their ILD.

Health-related quality of life

The mean (SD) KBILD total score for all patients was 55.3 (15.6). Twenty-two (38%) patients reported a deterioration in their respiratory health status, 14 (25%) patients reported an improvement and 21 (37%) patients were unchanged between visits (as rated by patients on the GRCQ scale). The KBILD questionnaire was a responsive instrument in those patients indicating a change in their health status. There was a significant change in KBILD total score between the two visits in patients reporting a change in GRCQ; mean (SD) 57.0 (13.6) versus 50.0 (9.7); mean difference 7.0; 95% CI 3.0 to 11.0; p<0.01. The anchors used in this study were significantly related to changes in health status. The change in KBILD score correlated with the change in GRCQ (r=−0.49) and FVC %predicted (r=0.41, both p<0.01).

Minimal clinically important difference

The mean (range) KBILD total score MCID was 5 (4–7) (table 2). The MCID of KBILD domains were 6 for Psychological, 7 for Breathlessness and Activities, and 11 for Chest Symptoms.

DISCUSSION

The KBILD scoring has recently changed with the introduction of a logit transformation step. The findings of our study support the KBILD logit version as a responsive questionnaire. The MCID for the KBILD total score (logit version) was determined by both anchor and distribution-based methods and was a change of 5 units.

A range of statistical techniques such as factor analysis, calculation of Cronbach's alpha, point biserial correlations and computing a raw score total are commonly used to develop questionnaire-based instruments for health and educational research.[14] There are significant limitations to using raw item responses that affect the precision of an instrument. The response scale is often not linear and it does not factor in the difficulty of the item or the ability of the person. The concept of linearity is one of the most fundamental ideas for Rasch Analysis, a form of Item Response Theory used by researchers to develop instruments. Rasch techniques offer a way to avoid these pitfalls and make use of raw test scores and rating-scale data to compute linear person measures. The term 'person measure' is the name of the Rasch scale number that expresses the performance of a respondent. Specifically, Rasch analyis allows researchers to use a respondent's raw test score and express the respondent's performance on a linear scale that accounts for the unequal difficulties across all test items. Rasch techniques involve corrections for a number of psychometric issues (eg, rating scales are ordinal, not all items assess the same part of the variable) so that accurate person measures can be computed. A 'logit' scale is used to express item difficulty on a linear scale that extends from negative infinity to positive infinity. For many analyses, item difficulties will range from −3 logits to +3 logits. Logit transformation of variables leads to the formation of a logit-normal distribution, which can be analysed with parametric tests. Furthermore, logit-transformed scores perform better at the extreme ends of a scale. Hence, logit transformation is being increasingly used in quality-of-life questionnaires.[15 16] We have previously reported that while logit scales lead to a numerical reduction in the change of health status scores, there is a very high correlation between KBILD logit and raw scoring methods.[4] We have also reported that the KBILD logit score version had construct validity, reliability and repeatability comparable with the raw score version.[5] As we expected, the MCID of the KBILD logit version was smaller than that reported for the raw score version (5 vs 8 units). From the patient's

perspective, the magnitude of the perceived change in health status remains the same; the lower MCID score for the logit version simply reflects the introduction of a logit transformation of patients' raw response scores.

MCIDs can be determined using a variety of methods. It is common practice to use multiple methods to improve the accuracy of the estimate. MCIDs can be determined by statistical/distribution methods (for example, SEM and effect sizes). The limitation of these methods is that they do not reflect the patients' perspective of change in their health status. This limitation can be overcome by adding anchor-based methodology. The anchors are patients' assessments and they can be objective or subjective. The advantage of subjective patient reported anchors is that they represent the patients' perspective, whereas the advantage of objective methods is that they are not susceptible to recall bias or unrelated variables such as the patients' mood. We used a range of methods to determine the MCID in our study; however, this can be expanded even further to include more measures in future. The MCID has been investigated for other health status measures in ILD. Swigris *et al*[11] investigated the MCID of the SGRQ and SF-36 using distribution (effect size and 1 SEM) and anchor (FVC, DLCO and dyspnoea) methods. Nolan *et al*[17] investigated MCID of incremental shuttle walk in idiopathic pulmonary fibrosis using distribution (0.5×SD and SEM) and anchor (GRCQ) methods.

There are some limitations to our study. The sample size for our study was small and this may have affected the validity of the MCID. It is possible that the GRCQ anchor may have been affected by recall bias due to the long follow-up period for some patients, that is, the GRCQ may reflect the follow-up KBILD score rather than its change. In order to minimise the effects of this recall bias, we included estimates of MCID using an objective measure, FVC, and also distribution methods, SEM and ES, which are not susceptible to bias. The MCID may vary according to the type of therapeutic intervention studied and the ILD condition. The MCID may also differ between those patients whose condition improved, compared with those who deteriorated. A recent, larger study that investigated the effects of pulmonary rehabilitation in ILD reported KBILD logit total score MCID of 4 units.[18] Our estimate for the KBILD MCID is therefore likely to be conservative. A larger study is required to determine the KBILD MCID, preferably with a standardised intervention, such as that within a clinical trial.

In conclusion, the KBILD is a quick and valid tool to identify health status issues important to patients. The MCID of the logit version of KBILD total score is 5 units. Our findings should facilitate the clinical interpretation of health status measures in ILD.

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