Validation of the Leicester Cough Questionnaire in Non Cystic Fibrosis Bronchiectasis

Maeve P Murray[1], Kim Turnbull[1], Shelley MacQuarrie[1], Joanna L Pentland[1] and Adam T Hill[1]

[1]Dept of Respiratory Medicine, Royal Infirmary of Edinburgh, Edinburgh, Scotland, UK.

Corresponding author:

Dr Maeve P Murray

Royal Infirmary of Edinburgh

Department of Respiratory Medicine

51 Little France Crescent

Old Dalkeith Road

Edinburgh

EH16 4SA

Email: maevemurray@hotmail.com

Phone: ++ 44 131 242 1921

Fax: ++ 44 131 242 1870

Short title: The LCQ in Bronchiectasis

Abstract

Health related quality of life is a potentially important marker for evaluating existing and new therapies in bronchiectasis. The Leicester Cough Questionnaire (LCQ) is a symptom specific questionnaire designed to assess the impact of cough severity, a major symptom of bronchiectasis. This study aimed to validate the LCQ in bronchiectasis.

1

The validity, responsiveness and reliability of the LCQ was assessed: ability to discriminate severe and mild disease; change in score following antibiotic treatment for exacerbations; repeatability over a 6 month period in stable disease; comparison with the St George's Respiratory Questionnaire (SGRQ).

120 patients (51 with severe disease, 29 with moderate and 40 with mild) completed the LCQ and SGRQ. The area under the receiver-operator curve was good for both severe and mild disease (0.84 and 0.80 respectively, P<0.0001). Following 2 weeks' antibiotic treatment, the LCQ score improved from 11.3(9.3-13.7) to 17.8(15-18.8) (P<0.0001). The LCQ score was repeatable over 6 months in stable disease [intraclass correlation coefficient of 0.96 (95%CI 0.93-0.97), P<0.0001]. Correlation between the LCQ and SGRQ scores was -0.7 in both stable disease and exacerbations (P<0.0001).

The LCQ can discriminate disease severity, is responsive to change and is reliable for use in non-cystic fibrosis bronchiectasis.

Word Count

Abstract: 197

Total count: 2, 865

Tables: 4 Figures: 3

References: 24

Introduction

Bronchiectasis, first described by Laennec in 1819, is a chronic debilitating condition, with abnormal permanent dilatation of the airways causing impaired mucus clearance, chronic bacterial infection and persistent bronchial inflammation [1]. Patients suffer from daily cough, excess sputum production and frequent exacerbations. They may also report breathlessness, wheeze and fatigue. Such debilitating symptoms impact on patients' health related quality of life [2, 3]. Improving patients' health related quality of life is a major goal of management.

Assessing health related quality of life allows the clinician to directly quantify the effect of disease on patients' daily life and is recognised as an important tool in the evaluation of both existing and new therapies [4, 5]. In chronic conditions, questionnaires targeting symptoms specific to the condition, exploring their physical effects, the subsequent restrictions in daily life and effect on mood are useful and relevant [6, 7]. They provide a unique integration of physical and psychosocial morbidity, unlike other clinical parameters.

The only validated questionnaire used in non-cystic fibrosis bronchiectasis is the St George's Respiratory Questionnaire (SGRQ) [3]. This was originally designed for use in chronic obstructive pulmonary disease (COPD) and assesses multiple symptoms, including dyspnoea, wheeze, cough and sputum production [8]. A symptom specific questionnaire focussing purely on cough and sputum expectoration, the major symptoms of bronchiectasis, would be an ideal measure of health related quality of life for bronchiectasis patients.

The Leicester Cough Questionnaire (LCQ) is a health related quality of life questionnaire validated for assessing chronic cough [9]. It is a 19 item self completed questionnaire exploring the impact of cough severity across 3 domains: physical (8 items), psychological (7 items) and social (4 items). The total severity score ranges from 3-21, with a lower score indicating greater impairment of health status due to cough. It assesses the impact of symptoms over the preceding two weeks and its potential has recently been explored in a

range of conditions including COPD, asthma and bronchiectasis [10]. No studies however, have focussed solely on non-cystic fibrosis bronchiectasis and it has not been validated for use in bronchiectasis.

The LCQ offers a pertinent, timely and useful clinical tool for bronchiectasis. It focuses purely on the impact of cough severity on HRQL, unlike other questionnaires that encompass multiple respiratory symptoms. Cough is the dominant symptom of bronchiectasis, present in up to 98% of patients and measuring its impact on HRQL is critical for both disease assessment and targeted management [11]. Additionally, the LCQ is concise, consisting of only 19 items, offering greater patient acceptance than lengthier questionnaires.

The aim of this study was to validate the utility of the LCQ as an assessment tool in non-cystic fibrosis bronchiectasis.

Methods

This was a 2 year prospective cohort study (2006-2008) in non-cystic fibrosis bronchiectasis approved by Lothian Research Ethics Committee. To validate the LCQ we explored its validity, responsiveness and reliability. For validity, we assessed the sensitivity, specificity, positive and negative predictive values, likelihood ratios and post-test odds as well as the area under the receiver operator curve in predicting both severe and mild bronchiectasis. In addition, we assessed the correlation of the LCQ with the SGRQ in stable disease and in exacerbations. For responsiveness, we assessed the change in LCQ score following antibiotic treatment for exacerbations. For reliability, we assessed change in LCQ score over a 6 month period when clinically stable.

Questionnaires

The LCQ is a 19 item self completed quality of life measure of chronic cough. It has 3 domains: physical (8 items), psychological (7 items) and social (4 items) [9]. The total severity score ranges from 3-21, with a lower score indicating greater impairment of health status due to cough. It assesses the impact of symptoms over the preceding two weeks.

The SGRQ is a 50 item self administered health related quality of life questionnaire consisting of 3 components- symptoms (8 items), activity (16 items) and impacts (26 items)- and has previously been validated to reflect impaired health related quality of life in bronchiectasis patients [3]. The total score ranges from 0-100, with a higher score indicating a poorer health related quality of life. It assesses the impact of symptoms over the preceding four weeks.

Validity

All patients with an established diagnosis of bronchiectasis based on both clinical history and computed tomography (CT) scan of the chest and who regularly attended the regional bronchiectasis clinic were invited to participate in the study.

Patients were recruited if they were clinically stable (defined as no requirement for antibiotics in the preceding 4 weeks) and had no exclusion criteria. All completed the LCQ and the SGRQ 24 hours prior to routine outpatient clinic attendance.

Exclusion criteria were: long term antibiotic therapy (oral or nebulised); current smokers and ex smokers of ≤2 years; coexisting COPD with FEV_1<60% predicted; a primary diagnosis of asthma; cystic fibrosis; active sarcoidosis, active allergic bronchopulmonary aspergillosis or active tuberculosis.

To predict severe and mild bronchiectasis, the following criteria were used:

Severe bronchiectasis was defined as meeting all of the following clinical, microbiological and radiological criteria: expectorating purulent sputum when stable assessed using a standardised sputum colour chart [12]; chronic sputum colonisation (defined as pathogenic bacteria cultured ≥2 sputum samples when clinically stable in the preceding 12 months) and at least 3 lobes affected on CT scan, with evidence of varicose or cystic bronchial dilatation in at least 1 lobe (for the purposes of this study, the lingula was considered as a separate lobe).

Mild bronchiectasis was defined as meeting all of the following clinical, microbiological and radiological criteria: expectorating mucoid or no sputum when clinically stable assessed using a standardised sputum colour chart [12]; evidence of cylindrical bronchiectasis on CT scan in ≤ 3 lobes; no evidence of chronic sputum colonisation.

All other patients were classified as having moderate bronchiectasis.

Responsiveness

Patients with exacerbations- defined as increasing cough, increasing sputum volume, worsening sputum purulence and a need for intravenous antibiotic therapy- were recruited. Both LCQ and SGRQ questionnaires were filled in immediately prior to commencing antibiotic treatment and one week following completion of treatment. Both questionnaires were adapted for the end of exacerbation assessment to ask about symptoms in the preceding week.

For patients who experienced more than one exacerbation, only the first exacerbation was used. All patients received 14 days of intravenous antibiotics treatment based on individual sputum bacteriology.

Reliability

The first 75 patients with clinically stable bronchiectasis (irrespective of disease severity) and who had had no changes to therapy made in the 6 months following entry to the study, were invited to repeat the LCQ 6 months following completion of the initial questionnaire.

Statistics

The utility of the LCQ in indicating severe and mild disease was assessed using sensitivity and specificity, positive predictive value (PPV), negative predictive value (NPV), likelihood ratio for a positive test (LR+) and likelihood ratio for a negative test (LR-) and the post test odds as well as the area under the receiver operator curve (AUC). The Kruskal-Wallis test compared severe bronchiectasis with moderate and mild bronchiectasis. The Wilcoxon test was used to compare scores at the start and end of exacerbations. The Spearman's rank correlation was used to assess correlation of the LCQ with SGRQ. For assessment of reliability over time, the intraclass correlation coefficient (ICC) was measured. A Bland-Altman plot was used to display repeatability over time [13]. Statistical analysis was performed using SPSS for Windows, Version 16 (SPSS inc, Illinois) and Graphpad Prism Version 5.0 (GraphPad Software, California). For interpretation of AUC values the

following   is widely accepted: AUC 0.50-0.59= no value of test; 0.6-0.69= poor discrimination value; 0.70-0.79= moderate discriminatory value; 0.80-0.89= good discriminatory value; 0.9-1.0= excellent discriminatory value [14]. A 2 tailed P value of <0.05 was statistically significant. Data is presented as median (interquartile range).

Results

Validity: the LCQ as a discriminant of severe bronchiectasis

120 patients were eligible for inclusion in the final analysis. Of these, 51 were classified as having severe bronchiectasis, 29 as moderate and 40 as mild. Table 1 details baseline characteristics for each group and Table 2 provides details of the aetiology of the bronchiectasis for each group.

In predicting severe bronchiectasis, the LCQ performed well, with an AUC of 0.84 (0.80-0.88, P<0.0001) (Figure 1). The lower the LCQ score the greater the likelihood ratio for severe disease (Table 3a). In predicting mild bronchiectasis, the LCQ performed well, with an

AUC of 0.80 (0.76-0.84, P<0.0001) (Figure 1). The higher the LCQ score the greater the likelihood ratio for mild disease (Table 3b).

The total and individual domain scores (physical, psychological and social) were significantly lower in those with severe disease compared with mild and moderate disease (Table 4).

The LCQ had a significant inverse correlation with the SGRQ in stable disease. The Spearman rank correlation coefficient was -0.7, (95% confidence interval -0.58 to -0.78, P<0.0001) (Figure 2a).

Responsiveness: the LCQ at the start and end of antibiotic treatment

32 exacerbations met the study criteria and were eligible for inclusion in the final analysis. 19 were due to *Pseudomonas aeruginosa* and 13 were due to other potentially pathogenic microorganisms (3 *Haemophilus influenzae*, 3 *Streptococcus pneumoniae*, 2 Methicillin Resistant *Staphylococcus aureus*, 2 *Moraxella cattarhalis*, 1 *Staphylococcus aureus*, 1 *Escherichia coli* and 1 *Serratia* species). There was a significant improvement (P<0.0001) in both the individual domain and total scores between the start and end of treatment. The actual domain scores at the start and end of treatment respectively were: physical domain [3.5(2.9-4) and 5.4(4.4-5.7)]; psychological domain [3.8(2.9-5) and 6.1(4.8-6.7)]; social domain [4(2.7-4.7) and 6.0(5.2-6.5)]. The total LCQ score at the start of treatment was 11.3(9.3-13.8) and at the end of treatment was 17.8(14.2-18.8). The changes for each patient are shown in Figure 3a. The LCQ had a significant inverse correlation with the SGRQ [Spearman rank correlation coefficient of -0.69 (95% confidence interval -0.53 to -0.81, P<0.0001 (Figure 2b)].

Reliability: the repeatability of the LCQ in stable bronchiectasis over a 6 month period

67(89.3%) patients repeated the LCQ 6 months following completion of the initial questionnaire. The intraclass correlation coefficient for the total LCQ score was 0.96 (95% confidence interval 0.93-0.97), P<0.0001. The mean difference between the total scores was

0.1 (-0.4 to 1.0). A Bland-Altman plot of the difference between repeat total scores for the LCQ is shown in Figure 3b.

Discussion

This study establishes the validity, responsiveness and reliability of the LCQ in non cystic fibrosis bronchiectasis. The validation of this HRQL questionnaire that explores the impact of cough severity is relevant to bronchiectasis and is likely to be of value in the evaluation of both existing and new therapeutic agents.

Health related quality of life questionnaires are well established useful measures of the direct impact of chronic respiratory disease on patients' daily life [15-17]. In chronic conditions, it has been increasingly recognised over the past decade that improving quality of life is important [4]. Achieving an improvement in HRQL is a major treatment target in bronchiectasis. However, to date there is a distinct paucity of validated questionnaires available to assess HRQL in non-cystic fibrosis bronchiectasis. There is no questionnaire that has been specifically developed for the disease and to our knowledge, there is only one validated questionnaire at present, the SGRQ, which was originally designed and intended to assess obstructive airways disease [3].

Cough is a cardinal symptom of bronchiectasis and as such may be most likely to impact on health related quality of life. A questionnaire that evaluates the effect of perceived cough

severity is highly relevant. The LCQ is a symptom specific questionnaire assessing cough and was selected for validation as it focuses solely on the dominant symptom of bronchiectasis and additionally, its potential utility in bronchiectasis has been highlighted in previous studies [10, 18]. Torrego et al explored the sensitivity of the cough reflex in bronchiectasis using inhalation of incremental doses of capsaicin and found that capsaicin sensitivity correlated positively with the total LCQ score (r=0.64, P=0.005) [18]. More recently, since the completion of this study, Polley et al have compared the LCQ and the Cough Quality of Life Questionnaire together with a generic health status questionnaire (the EUroQol) in different chronic respiratory diseases- including bronchiectasis- and suggested the LCQ may be able to provide useful information about the impact of cough [10, 19, 20]. The LCQ itself is more concise than other health related quality of life questionnaires assessing cough which may imply greater patient acceptance of the questionnaire [9].

The three key concepts required to ensure a questionnaire is valid for a disease are: validity, responsiveness and reliability. Our study included all patients with an established diagnosis of bronchiectasis attending a specialist clinic. We then selected patients at different ends of the spectrum- mild and severe bronchiectasis- to establish whether the LCQ could demonstrate convergent validity using selected relevant markers of mild and severe disease respectively. There are no previously established criteria defining disease severity in bronchiectasis. The criteria we used to define mild and severe disease were based on our clinical experience of non-cystic fibrosis bronchiectasis and incorporate the major features of the disease including radiological severity, microbiological history and clinical symptoms. Aspects of these key features have, in previous studies been independently associated with health related quality of life- Wilson et al explored whether sputum bacteriology affected health related quality of life and found that patients colonised with *Pseudomonas aeruginosa* had a significantly worse SGRQ score than other patients with *Haemophilus influenzae* or no

bacterial growth (P<0.05)[21]. Martinez-Garcia et al found in their cohort of Spanish patients with non-cystic fibrosis bronchiectasis that dyspnoea, FEV_1 and sputum expectoration were associated with a worse SGRQ score [2]. We found that the LCQ performed well for predicting both severe and mild disease. In clinical practice, however, the main value of the LCQ will be in the longitudinal assessment of disease and in the evaluation of existing and new therapies.

To our knowledge, the SGRQ is the only previously validated health related quality of life questionnaire in non-cystic fibrosis bronchiectasis [3]. We therefore used this as a standard against which to assess the LCQ. We found the LCQ total score had a significant negative correlation with the total SGRQ score in both stable disease and exacerbations, further corroborating the validity of the LCQ in non-cystic fibrosis bronchiectasis. The correlation is, however, imperfect suggesting that the two questionnaires are providing information on different aspects of the impact of bronchiectasis on health related quality of life.

The LCQ confers advantages over the SGRQ in bronchiectasis. The LCQ focuses on cough, the major symptom of both stable disease and exacerbations, making it highly relevant. The SGRQ assesses other clinical features in addition to cough such as dyspnoea and wheeze, symptoms which are less frequently present in bronchiectasis- a previous study found that dyspnoea was present in only 62% of patients at presentation compared with cough in 98% [11]. The LCQ is concise with only 19 items for completion compared with 50 items contained within the SGRQ and will be easier to complete particularly if repeated testing is required, for example, in response to exacerbations. Furthermore, the LCQ assesses symptoms over a shorter time period (2 weeks) compared with 4 weeks in the SGRQ. The validation of the LCQ in bronchiectasis in addition to the SGRQ will provide two relevant and important means of assessing the impact of daily symptoms on HRQL. Improving HRQL is a major aim of management in chronic disease.

There was a significant improvement across all domains and the total LCQ score in direct response to 2 weeks' intravenous antibiotic treatment for exacerbations with a median improvement in total score of 4.6(3.2-7.2) units following completion of treatment. Mutalithas et al found a significant improvement in all domains of the LCQ following 4 weeks of outpatient based physical therapy intervention- total score improving form 14.2 to 17.3, P<0.0001 [22]. There is debate regarding the minimal important difference in total LCQ score thought to be clinically relevant, with previous studies assessing the LCQ in chronic cough suggesting a change of between 1.3 and 2.7 units [23, 24]. This study did not address the minimally important difference and further studies are needed.

The reliability of the LCQ was measured by assessing its repeatability over 6 months, a period longer than the 2 week time course used in the initial development and validation of the questionnaire [9]. 6 months is representative of the routine follow up period for patients with stable non-cystic fibrosis bronchiectasis. It is expected that there is some noise in health related quality of life questionnaires but in clinically stable bronchiectasis the scores were repeatable over a 6 month period with a high intraclass correlation coefficient. The mean change for clinically stable patients over 6 months was 0.1(-0.4 to 1.0) units, lower than the minimal important differences found in the previous studies.

This study validates the LCQ for use in the assessment of non-cystic fibrosis bronchiectasis. It is able to discriminate disease severity, is responsive to change and is reliable. It assesses one of the most pertinent symptoms of bronchiectasis and is likely to be of value in assessment of both existing and new therapies as well as providing a relevant adjunct to current clinical management. Further studies to externally validate the LCQ in bronchiectasis would be welcome.

Acknowledgements

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Figure Legends

Figure 1 Legend

Figure 1. Validity of the LCQ: Receiver Operator Curve in severe bronchiectasis

(AUC=0.84) and in mild bronchiectasis (AUC=0.80). Total LCQ Score cut off values used:

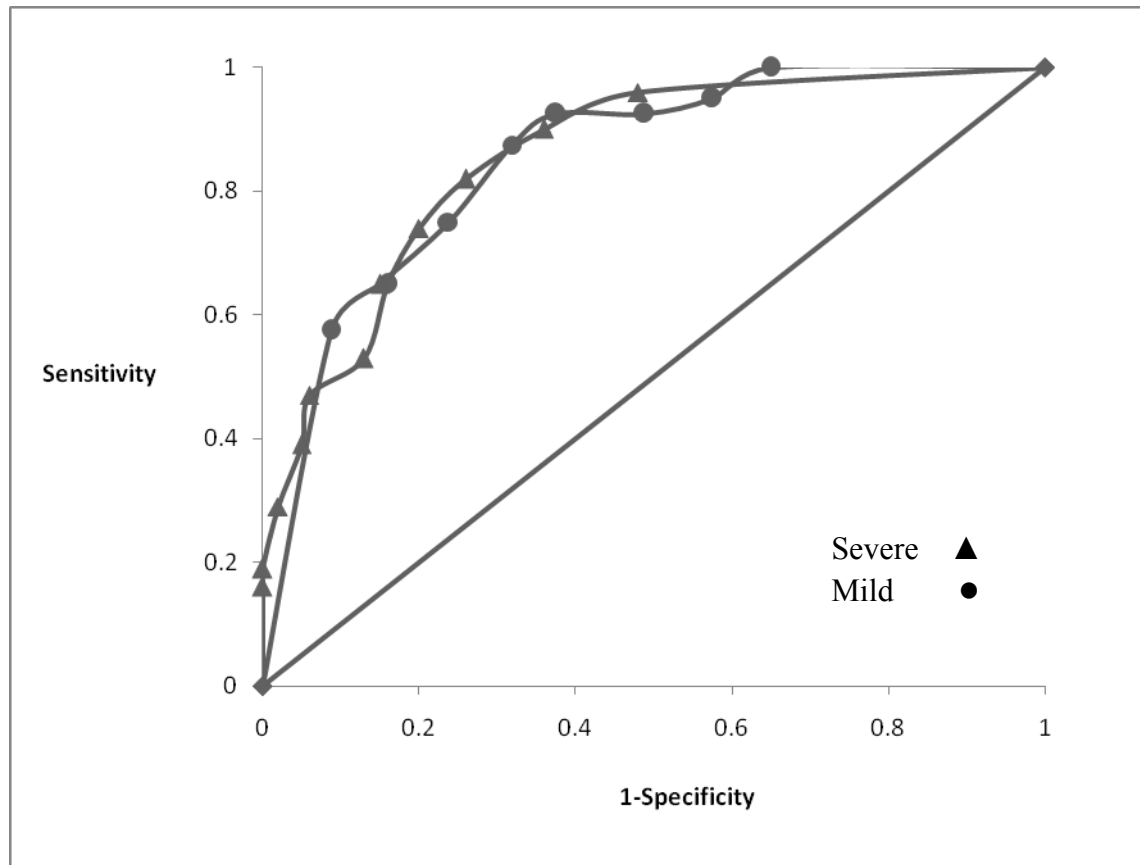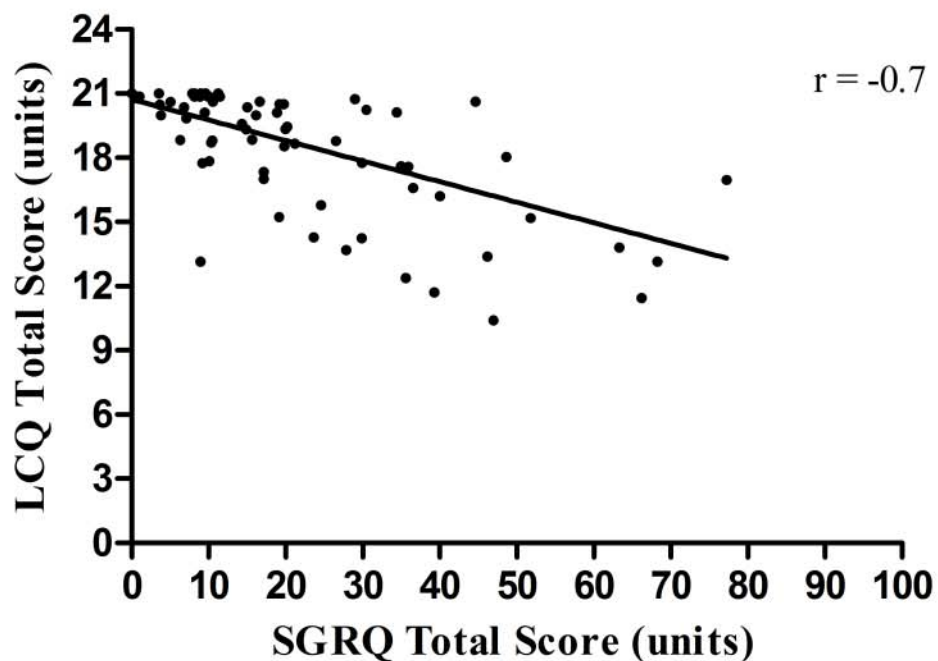3-5; 6-8; 9-11; 12-14; 15-17; 18-21. Straight line (AUC=0.5).

Figure 1.

Figure 2 Legend

2a) Validity of the LCQ: correlation of the LCQ total score with the SGRQ total score in

stable bronchiectasis.

2b) Validity of the LCQ: correlation of the LCQ total score with the SGRQ total score in

exacerbations.

Correlation of the LCQ and the SGRQ total scores in stable bronchiectasis

r = -0.7

Correlation of the LCQ and the SGRQ total scores in exacerbations
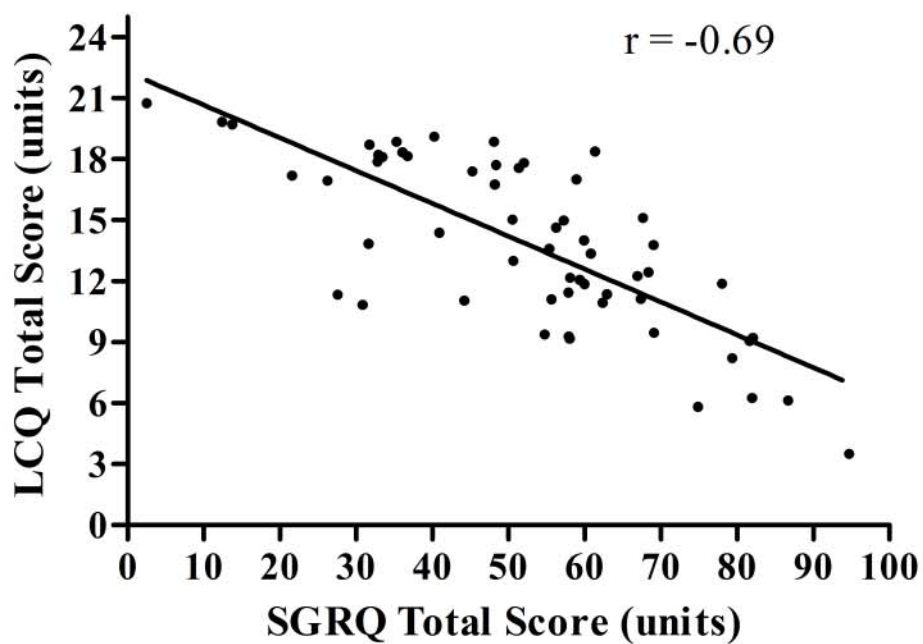

r = -0.69

Figure 3a and 3b Legend

3a) Responsiveness of the LCQ: total score before and after 2 weeks' intravenous antibiotic

in 32 exacerbations. Median values for start and end are shown (see ➡).

3b) Bland-Altman plot of Leicester Cough Questionnaire total score repeated over 6 months

in 67 patients with stable bronchiectasis. The solid line represents the mean difference

between the 2 scores (-0.23) and the perforated lines represent the upper and lower 95%

limits of agreement (-2.6-2.1).

3a) Total LCQ Score at start and end of exacerbation
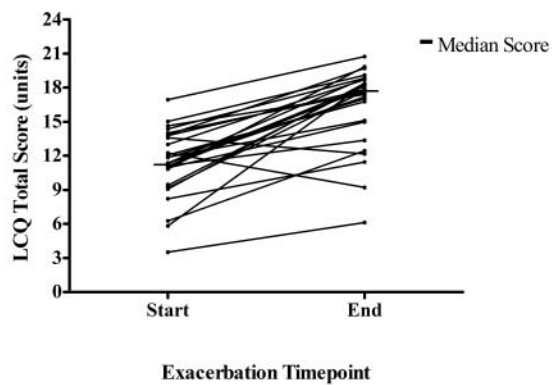
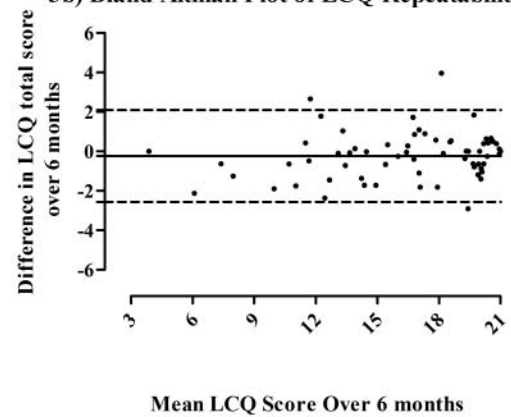3b) Bland-Altman Plot of LCQ Repeatability

Table 1 Patient Characteristics

Charactersitic	Severe Bronchiectasis n = 51	Moderate Bronchiectasis n = 29	Mild Bronchiectasis n = 40	P
Male	25 (49%)	10 (34.5%)	16 (40%)	0.4
Age	68 (60-74)	69.5 (56.2-77.2)	67 (59-76.7)	0.9
Ex-Smokers	18 (35%)	9 (31%)	15 (37.5%)	0.9
Pack Year History	0 (0-8)	0 (0-2.5)	0 (0-7)	0.7
FEV_1 (L)	1.55 (1.30-2.15)	1.8 (1.34-2.47)	2.3 (1.9-2.7)	0.002
% Predicted FEV_1	69 (47-86)	78.2 (69.7-89.6)	82.5 (71.5-96)	0.006
FVC (L)	2.45 (1.80-3.20)	2.55 (2-3.19)	3.06 (2.5-3.5)	0.04
% Predicted FVC	77(61- 93)	85.9 (85-100)	90 (78.5-106)	0.01
FEV_1/FVC ratio %Predicted	0.68 (0.58-0.77)	0.76 (0.65-0.85)	0.74 (0.66-0.82)	0.01
FEV_1 / FVC	89(73-97)	94 (85-105)	94.9 (86-102)	0.09
% with purulent sputum when stable	100	14	0	<0.0001
% Chronically Colonised	100	58.6	0	<0.0001
% Chronically colonised with *Pseudomonas aeruginosa*	51.0	47.0	0	<0.0001
% with cystic bronchiectasis on CT scan	62.7	10.3	0	<0.0001
No. lobes affected	5 (4-6)	4 (1.5-5)	2 (1-3)	<0.0001
No. of outpatient exacerbations in preceding 12 months	3 (1.75-5.25)	1 (0-3)	0 (0-1.25)	<0.0001

Data presented as median (interquartile range)

Table 2 Aetiology

Aetiology	Severe bronchiectasis (n=51) %	Moderate Bronchiectasis (n=29) %	Mild bronchiectasis (n=40) %
Idiopathic	14	45	38
Post-infective	47	35	43
Post- Pulmonary Tuberculosis	12	17	7
Allergic Bronchopulmonary Aspergillosis	17	3	5
Inflammatory Bowel Disease	2	0	0
IgG subclass deficiency	2	0	5
Ciliary Dyskinesia	2	0	0
Sarcoidosis	4	0	2

Table 3a. Utility of the LCQ Predicting Severe Disease

LCQ Score	Sensitivity	Specificity	LR+	LR-	Post-Test Odds Ratio	Positive Predictive Value	Negative Predictive Value
≤ 10	29.4	98.5	19.6	0.7	14.5	93.7	65.4
≤ 11	39.2	95.6	8.9	0.6	6.6	87	68
≤ 12	47	94.2	8.1	0.5	6.0	85.7	71
≤ 13	52.9	86.9	4.0	0.5	3.0	75	71
≤ 14	64.7	84.0	4.0	0.4	3.0	75	76
≤ 15	74.5	79.7	3.7	0.3	2.7	73	81

Prevalence = 42.5% and pretest odds ratio =0.74; LR+ = the likelihood ratio for a positive test result and LR- = the likelihood ratio for a negative test result.

Table 3b. Utility of the LCQ Predicting Mild Disease

LCQ Score	Sensitivity	Specificity	LR+	LR-	Post-Test Odds Ratio	Positive Predictive Value	Negative Predictive Value
≥ 20	57.5	91.2	6.5	0.5	3.3	76.7	81.1
≥ 19	65	85	4.3	0.4	2.2	68.4	82.9
≥ 18	75	76.2	3.15	0.3	1.6	61.2	85.9
≥ 17	87.5	68.7	2.8	0.18	1.4	58.3	91.7

Prevalence = 33.33% and pretest odds ratio = 0.5. LR+ = the likelihood ratio for a positive test result and LR- = the likelihood ratio for a negative test result.

Table 4 Leicester Cough Questionnaire Scores

Domain	Severe Bronchiectasis n = 51	Moderate Bronchiectasis n = 29	Mild bronchiectasis n = 40
Physical	4.4 (3.4-5)	5.5 (4.4-6.2)	6.1 (5.2-6.7)*
Psychological	4.4 (3.3-5.3)	5.9 (4.8-6.8)	6.8 (5.7-7.0)*
Social	4.5 (3.5-6.0)	6.0 (5.0-6.9)	6.7 (6.0-7.0)*
Total	13.6 (10.4-16.2)	17.8 (14.02-19.9)	19.3 (16.9-20.6)*

*p<0.0001; Data presented as median (interquartile range)