Service Evaluation: Bronchoscopic lung volume reduction using endobronchial valves for the symptomatic improvement of emphysema

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INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) includes chronic bronchitis and emphysema, and is a major source of mortality and morbidity globally. It presents a significant healthcare burden. The British Thoracic Society reported that 27,000 people die annually from COPD, and that respiratory disease kills one in five people in the UK. The cost to the NHS for managing COPD was £6.6 billion in 2004.[1] This disease area is important not only for the reasons outlined above but also because improving the management of long-term conditions is an NHS priority.[2]

Emphysema is characterised by permanent and irreversible enlargement of air spaces, accompanied by destruction of alveolar walls.[3] In emphysema the forced expiratory volume in one second (FEV_1) is considerably decreased and the total lung capacity (TLC) and residual volume (RV) are increased.

Figure 1: An example of the Zephyr® endobronchial valve used in bronchoscopic lung surgery.

The current therapeutic options for COPD are smoking cessation, pulmonary rehabilitation and pharmacological therapies. Pharmacological therapies include bronchodilators and corticosteroids, which aim to decrease airway resistance and airway inflammation. However, conventional treatments show limited effectiveness against the hyperinflation and decreased elastic recoil associated with emphysema.[4]

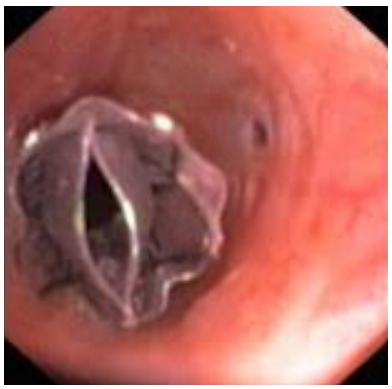

Figure 2: An inserted Zephyr® endobronchial valve shown opening during expiration.

Patients with severe emphysema who achieve inadequate symptom control using the therapies outlined above may be selected to undergo bronchoscopic endobronchial valve insertion. Endobronchial valves (Figures 1-2) allow drainage of air and secretions from the distal lung segment at expiration, while blocking air entry at inspiration, resulting in a redirection of airflow away from the blocked segments.[5] Several randomised controlled trials and studies have shown that

endobronchial valves improve lung function, dyspnoea symptoms and exercise tolerance.[6-8] The long-term outcomes of valve insertion are variable and influenced, among other factors, by emphysema type.

The criteria for performing endobronchial valve insertion in patients at a teaching hospital in Bristol include high disease impact by FEV1 < 50%, RV > 175%, breathlessness (mMRC dyspnoea grade), presence of intact fissures (Figures 3-4) between lobes at the intended site of valve insertion, and absence of interlobar collateral ventilation as measured by the Chartis Pulmonary Assessment System™.[9,10] The importance of fissure completeness has been illustrated in two studies.[6,11] A sub-analysis of the VENT trial showed a more favourable response to valve insertion in those with intact fissures with regards to improvement in lung function tests,[6] and a non-randomised study[11] demonstrated longer-lasting improvements following endobronchial valve insertion in

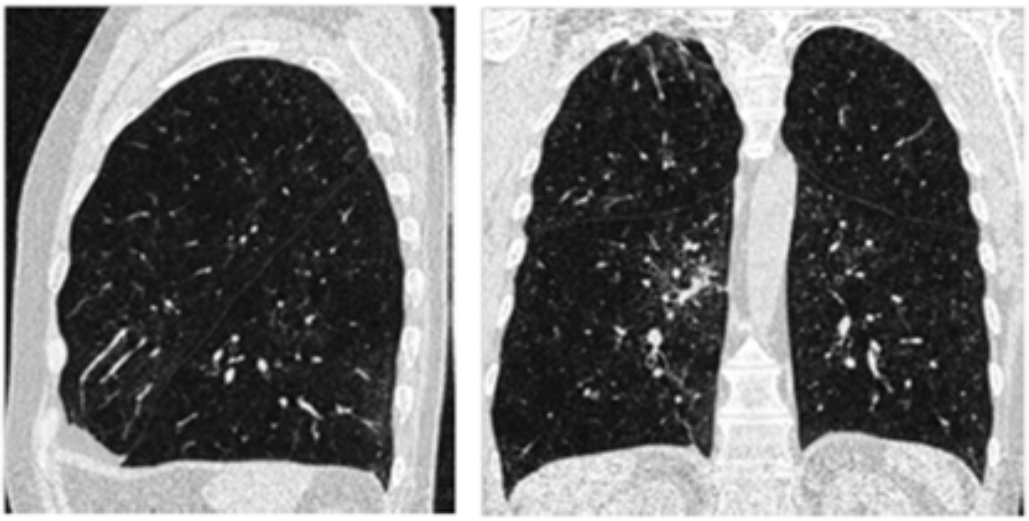

Figure 3: Complete (intact) inter-lobar fissure on both sides. The patient is likely to respond to insertion of endo-bronchial valves

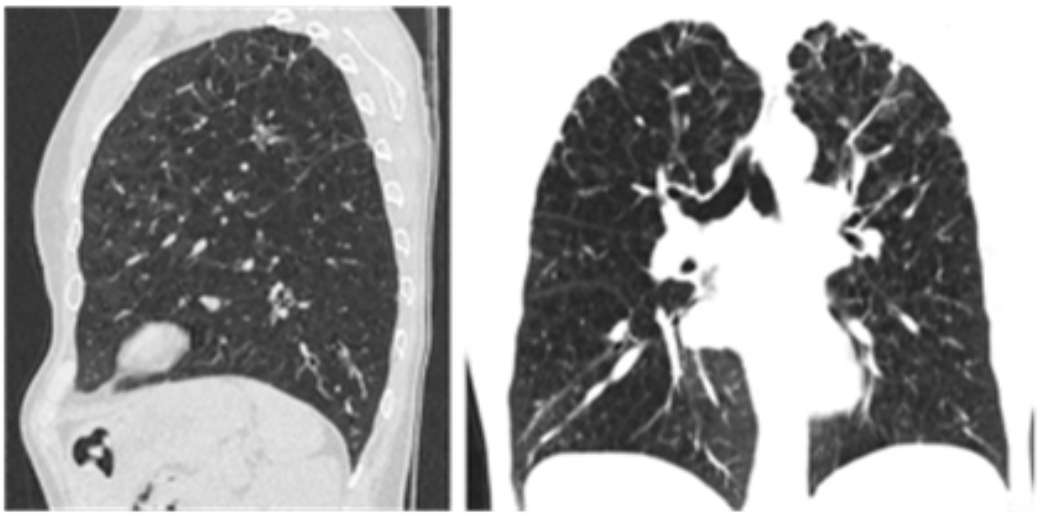

Figure 4: Incomplete fissure between the left upper and the left lower lobe. The patient is not likely to respond to insertion of an endo-bronchial valve in either lobe

those with intact fissures.

Patients indentified to undergo this procedure locally fulfil the selection criteria, but not all patients respond to therapy, specifically those with significant bullous emphysema. This observation has prompted an enquiry to identify the clinical characteristics that are commonly associated with positive outcomes in endobronchial valve insertion. It was felt locally that this would be best addressed by undertaking a service evaluation.

A retrospective analysis of 26 patients that had undergone Zephyr® endobronchial valve insertion at the teaching hospital between June 2013 and December 2014 was undertaken. It is hoped that this information may be used to inform future patient selection for endobronchial valve insertion locally.

AIM :

To identify the clinical differences between radiological responders and non-responders in a cohort of patients that have undergone endobronchial valve insertion.

OBJECTIVES:

1. To assess baseline data including forced expiratory volume in one second (FEV_1 % predicted), residual volume RV (L), Kco (% predicted), six minute walking distance (6MWD), COPD Assessment Test (CAT) and mMRC dyspnoea grade in a cohort of patients that have undergone endobronchial valve insertion, to determine clinical differences between radiological responders and non-responders to valve surgery.
2. To compare baseline respiratory and functional test data against 4 to 6 week follow-up data to determine if there has been an improvement.
3. To determine if a difference in respiratory and functional outcomes exists between responders and non-responders
4. To determine if the presence of large bullous emphysema confers a poor radiological or clinical response.

METHODS

Patients were selected for surgery using stringent selection criteria (Table 1) and a Multidisciplinary Team (MDT) assessment involving a respiratory physician, thoracic surgeon and thoracic radiologist.

Table 1. Main Inclusion/Exclusion Criteria

INCLUSION

- HRCT scan indicates heterogeneous emphysema > 15%
- HRCT scan indicates interlobar fissure completeness > 90%
- Collateral ventilation negative
- FEV1 15% - 45% of predicted
- TLC > 100% of predicted
- RV >175% of predicted
- mMRC ≥ 3 (0–4)
- CAT Score ≥ 15
- 6 minute walk distance 140 – 450 m
- Stopped smoking for > 6 months prior to entering the study

EXCLUSION

- Current smokers
- Raised Pulmonary Artery Pressure > 50 mmHg
- Bronchiectasis
- Severe co-morbid conditions
- Inability to walk > 140 m in 6 min

Inter-lobar fissure completeness of the target lobe was a requirement for surgery.[10] Fissure completeness was assessed using three-dimensional high resolution thin contiguous cut thoracic computed tomography (3D HRCT). Patients were enrolled to the procedure when a thoracic radiologist and a respiratory physician agreed that fissure completeness was over 80%. Patients also underwent baseline assessments of lung function including FEV_1 (% predicted), [12] RV (L), [13] 6MWD, [14] CAT score (Appendix 1) and mMRC grade (Appendix 2). $Alpha_1$-antitrypsin (A1AT) deficiency status was noted. Flow analysis was carried out in 17/25 patients at the time of procedure using the Chartis Pulmonary Assessment System™ (Figure 5).

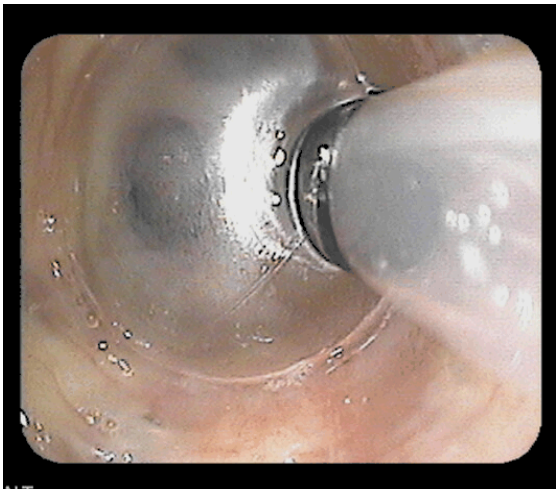

Figure 5: A Chartis catheter in situ.

Flow analysis was not carried out on all patients, since at that time there was minimal information available on the significance of collateral ventilation. The graphs (Figures 6-8) for Chartis results were examined and patients were identified as cross-ventilation negative (no collateral ventilation) when a flow decline

was identified, otherwise they were classified as cross-ventilation positive (evidence of collateral ventilation).

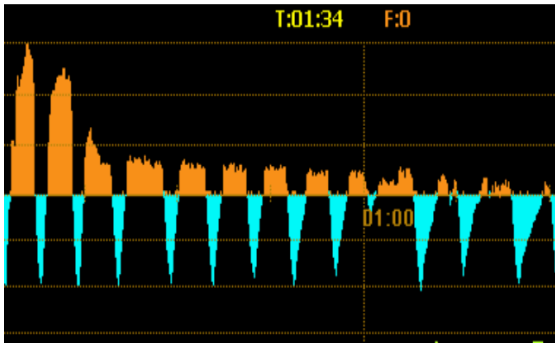

Figure 6*:* A Chartis graph examining collateral flow where the orange trace is expiratory flow. This graph shows a decline in flow over time indicating no collateral ventilation (collateral ventilation negative).

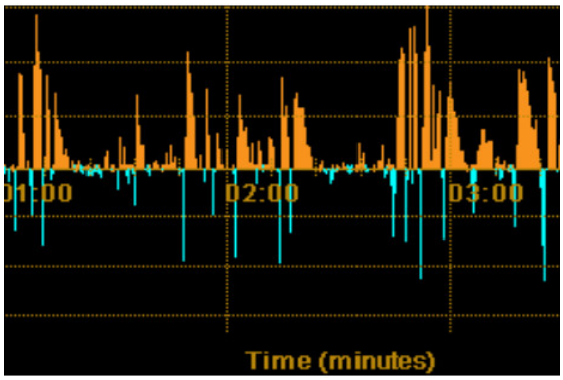

Figure 7*:* A Chartis graph showing unchanged flow over time indicating a presence of collateral ventilation.

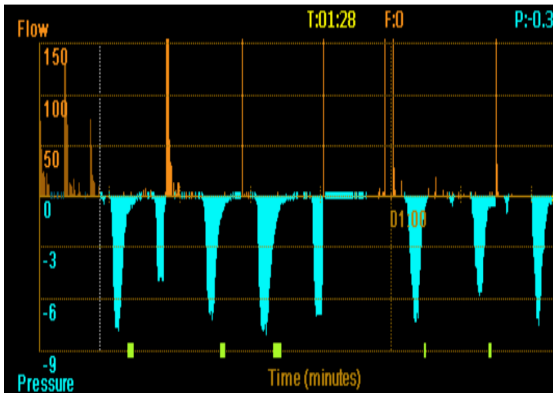

Figure 8: A Chartis graph showing the absence of flow typically seen in bullous emphysema in low flow.

Selected patients were grouped into those with bullous emphysema and those with non-bullous emphysema as evidenced by a visually prominent bullous component on the target lobe on 3D HRCT, according to respiratory physician and respiratory radiologist assessment.

FOLLOW-UP AND OUTCOME MEASURES

All patients were assessed for post-operative radiological response using HRCT scans at 4 to 6 week follow-up (Figure 9). Patients were divided into groups of responders and non-responders. A responder was defined as someone in whom volume loss of the target lobe was complete (100%), measured as a loss of 350ml of volume in the affected lung; or partial (over 50%), indicating a sub-total collapse of the target lobe. A non-responder was defined as someone with no evidence of target lobe collapse following valve insertion. Patients were re-evaluated with pulmonary function tests, exercise tolerance tests and a quality of life assessment, and adverse events were noted. The primary efficacy endpoint was defined as a radiological response (collapse) of the target lobe. The secondary efficacy end-points were the improvement from baseline in FEV_1 (% predicted), RV(L), CAT score, 6MWD test and mMRC dyspnoea grade.

Figure 9A

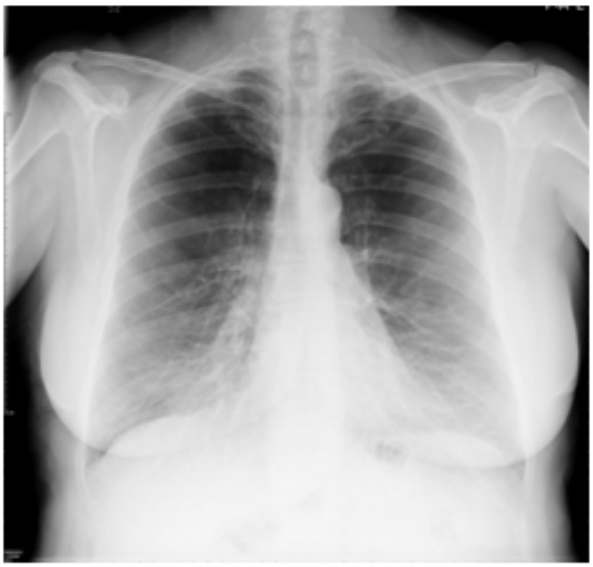

Figure 9C

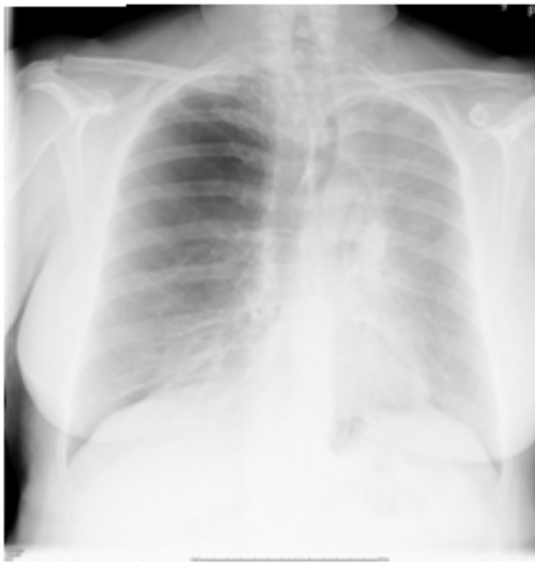

Figure 9B

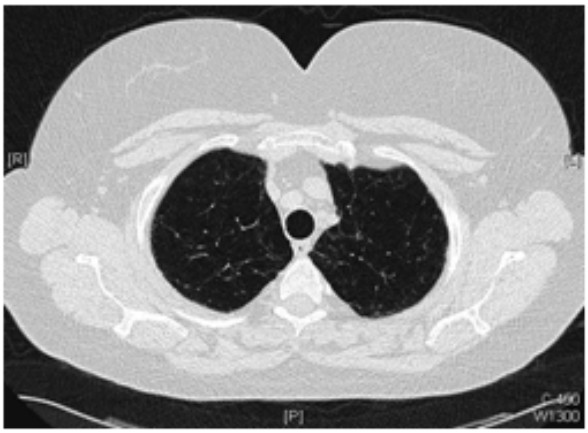

Figure 9D

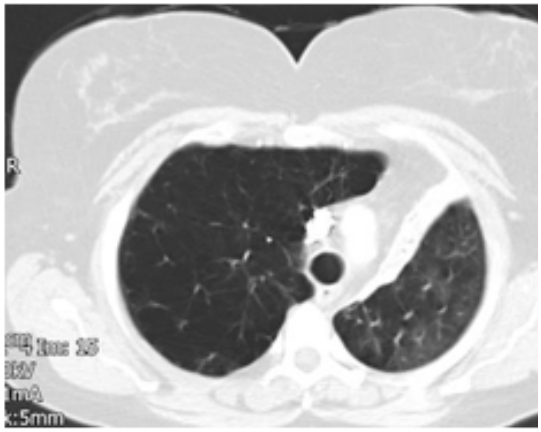

Figure 9A-D. 9A-B Chest radiograph and HRCT showing emphysematous lung pre-insertion of valve. 9C-D Chest radiograph and HRCT showing collapse of the left upper lobe post insertion of valve. Patient classed as a full responder.

STATISTICAL ANALYSIS

The Mann Whitney U test was used to assess the significance of differences between responders and non-responders at radiological baseline. The paired t-test was used to assess pre- and post-operative lung function test results e.g. FEV_1 and RV. The Wilcoxon Signed Rank test was used to assess pre- and post-operative CAT score and mMRC grade. A value of $P < 0.05$ was considered to indicate statistical significance.

The Fisher's Exact test and Chi-square were used for categorical analysis, to compare rates of response according to presence or absence of collateral ventilation, and presence or absence of paraseptal bullae.

RESULTS

26 patients were reviewed. Of these, 25 patients had post-operative CT scans available at 4 to 6 week follow-up. One patient did not return for post-operative review. Out of 25 patients, 14 demonstrated complete radiological response, two patients

demonstrated a partial radiological response, and nine showed no radiological response (Figure 10). For the purpose of further analysis responders and partial responders were grouped in a single category, named Responders.

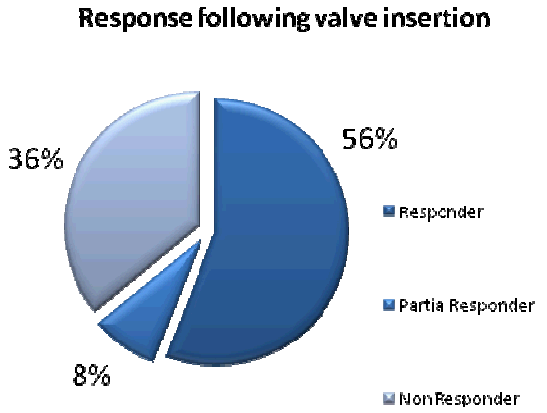

Figure 10: Pie chart showing the proportion of patients who were classed radiologically as responders (14/25), partial responders (2/25) and non-responder (9/25) to endobronchial valve insertion. n=25

The mean age at surgery in those with radiological response was 62 years (range 43-79), and in those that did not respond, 64 years (range 40-78) (p = 0.447). The median follow-up period was 34 days (range 12-60 days). When comparing responders and non-responders a significant difference was identified between the two groups with respect to the presence of paraseptal bullous emphysema (Figure 11).

Evidence of significant bullous emphysema was seen more frequently in the non-responder group (7/9) compared to the responder group (2/16) (p = 0.002) (Figure 12)

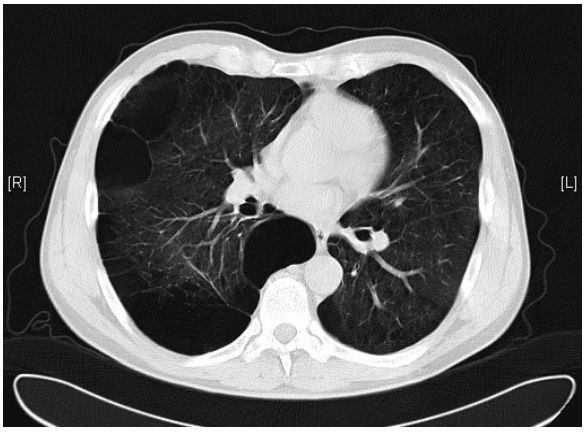

Figure 11: HRCT showing a patient with evidence of paraseptal bullous emphysema in the right upper lobe.

A significant difference was also identified between the two groups with respect to evidence of collateral ventilation as seen on Chartis analysis. Of the patients with Chartis data available (17 patients) a decline in flow over time occurred more frequently in the responder group (Figure 13) post-procedure (9/10) compared to non-responders (2/7) (p = 0.035). This difference was identified as being statistically significant. Of the 5/25 patients with A1AT deficiency only 2/5 (40%) demonstrated a radiological response to endobronchial valve insertion compared to 14/20 (70%) patients that did not have A1AT deficiency.

There was no significant difference identified between radiological responders and non-responders when comparing mean age, gender, FEV_1 or RV at baseline. Mean FEV_1 in those that demonstrated radiological response was 28%, and 31% in those with no radiological response (p = 0.327). Mean RV (%

predicted) was 237 in those that demonstrated radiological response, and 227 with no response (p = 0.928).

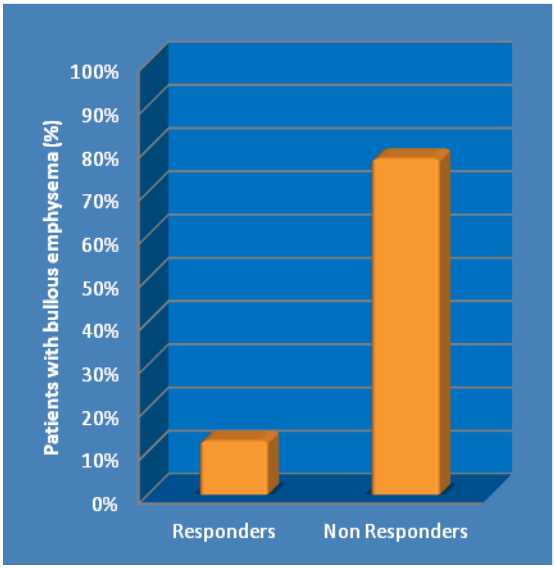

Figure 12: A column graph comparing the percentage of patients with bullous emphysema between the responder group (2/16) and non-responder group (7/9). n=25

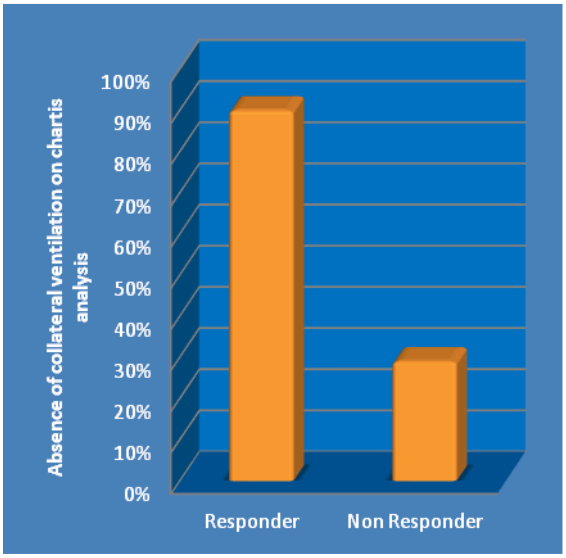

Figure 13: A column graph comparing the absence of collateral ventilation on Chartis pulmonary catheter analysis between the responder group (9/10) and non-responder group (2/7). n=17.

A difference was identified between the two groups with respect to a change in FEV_1 (% predicted) following the procedure. There was a statistically significant improvement in FEV_1 in the responder group, mean FEV_1 22% (P = 0.00778) compared to the non-responder group mean FEV_1 -7% (p = 0.566). A difference between the two groups was also identified with respect to RV(L), where mean RV(L) in those that demonstrated radiological response was -0.5L (p = 0.272) compared to non-responders -0.4L. The mean change in Kco (% predicted) in radiological responders was 30% and was statistically significant (p = 0.0074) compared to the non-responder group 13%. The mean change in mMRC grade in responders was -0.22, and in non-responders -0.4. The mean change in CAT score in responders was -8, and in non-responders -3. The statistical significance of many of the post-operative outcomes could not be calculated owing to the small sample size at follow-up (Figure 14).

Regarding safety, one patient expectorated the valve and one patient died on the fifth day of the procedure following 'complications' (pneumothorax and pneumonia) defined as events needing hospitalisation, causing a deterioration in health, or death (Table 2). No adverse events were attributed to using Chartis.

Table 2. Complications within 30 days of procedure

	EBV n=26
COPD exacerbations	6 (23.1%)
Pneumonia	3 (11.5%)
small volume temporary haemoptysis	4 (15.4%)
Pneumothorax	3 (11.5%)
Valve migration	1 (3.8%)
Death (complication of pneumothorax and pneumonia)	1 (3.8%)

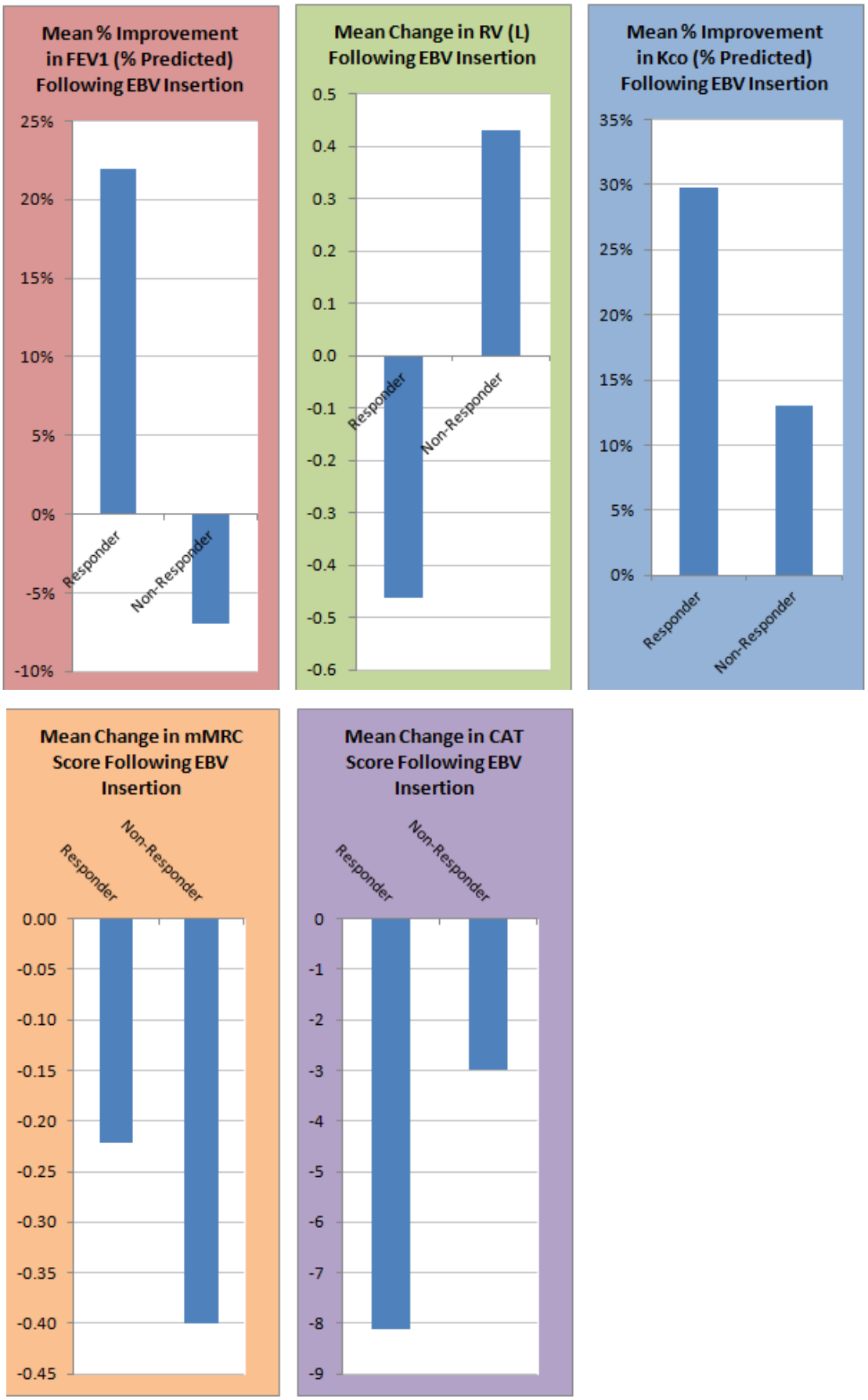

Figure 14: A summary of results showing mean percentage improvement and mean changes for a variety of respiratory outcome measures in radiological responders versus non-responders.

DISCUSSION

The results demonstrate significant improvement in clinical outcomes at 4 to 6 week follow up in those with total or sub-total target lobe collapse. The mean percentage change in FEV1 (% predicted) and change in RV (L) in radiological responders correlate with the results of the BeLieR-HIFi study (FEV_1 22% and RV(L)-0.5) and support our findings.[15]

Patients with the presence of paraseptal bullous emphysema were seen more frequently in the non-responder group than the responder group, which suggests that significant bullous emphysema in the target lobe may be associated with a reduced response to endobronchial valve insertion. This finding suggests that endobronchial valve insertion may need to be used with caution in such patients. The association between the presence of paraseptal bullous emphysema and a worse response does require further investigation.

Factors that are associated with a good response to endobronchial valve insertion include the absence of collateral ventilation, identified using the Chartis system. Patients that exhibited a decline in flow over time, which suggests an absence of collateral ventilation, were more likely to respond as shown by a total collapse of the target lobe. This is well documented and was the rationale for using the Chartis catheter in this study.[16] This is an important finding since it assists with the identification of patients that are more likely to respond to endobronchial valve insertion.

This evaluation also suggests that A1AT deficiency may be associated with a poorer response to endobronchial valve therapy. However, more recently a randomised controlled trial has shown that A1AT deficient patients do appear to respond to bronchoscopic lung volume reduction.[17] Outcomes in these patients therefore requires further investigation.

The change between pre- and post-operative dyspnoea mMRC score was very small and the statistical significance could not be tested. This is a not uncommon issue when analysing mMRC results. A similar difficulty was encountered with the evaluation of changes to the CAT score. Furthermore, some patients were lost to 4 to 6 week follow-up, resulting in a very small sample size for this analysis. This particularly affected the non-responder group, such that quality of life and functional improvement could not be fully evaluated. However, from the data that was available, changes in these functional outcomes were minimal. This could, in part, be due to post-surgical recovery, which may be a confounding factor upon such outcome measures where the follow-up period is short. Longitudinal data is required for an adequate evaluation of these outcomes. Post-operative 6MWD could not be assessed owing to a significant number

of subjects stopping before six minutes. Many of these subjects reported tiredness and limb discomfort. It was considered inappropriate to extrapolate the results to six minutes as the distance covered in the first few minutes is known to be greater than the distance covered towards the end.

A recommendation is to revisit this study as more patients undergo the procedure at the Trust and to generate longitudinal data to review long-term outcomes. This would also help us to understand any other impact the intervention is having, i.e. how long these improvements last, or whether the lobes remain deflated, or whether there are ongoing lung changes that mean endobronchial valves only last for a finite period.

LIMITATIONS

There were several limitations with this evaluation. Firstly the study was small and there was inadequate follow-up data; therefore definitive conclusions cannot be drawn. Of the data used to inform this analysis, only 62.9% was available from a treatment specific departmental proforma (Appendix 3). A further 12.9% was sourced directly from the patient notes and from an electronic clinical database. However, 24% of the data required for analysis was not present. This not only affects the analysis but also highlights issues in continuity and maintenance of records across different databases within the Trust. Secondly, the short-term follow-up period (4 to 6 weeks), the period for which there was the greatest volume of hospital data can only tell us whether the surgery successfully reduced lung volume. This short interval may be inadequate for the evaluation of symptom improvement, since the patient may need a recovery period that exceeds this. Furthermore, long-term benefits were not assessed. This study is limited by its retrospective design wherein follow-up periods beyond routine clinical review at 4 weeks, were not agreed leading to an absence of longer-term follow-up data. Longitudinal data or a study period of at least 6 months is needed in order to evaluate long-term outcomes. Thirdly, we used lung collapse as our primary efficacy end point and marker of treatment response. Baseline functional data (mMRC grade and/or CAT score) was collected, but there was insufficient follow-up data for us to compare these to radiological response in all cases. However, how the patient feels and functional improvement such as a reduction in breathlessness post-endobronchial valve insertion may be the best outcome to measure. Radiological response, although it will likely correlate with functional response, has not been examined adequately in this study; therefore we cannot be sure that the patients that were classed as responders have actually improved symptomatically. Finally, there is an absence of data regarding the duration of improvement seen with valve insertion or

whether ongoing lung changes have an effect on this.

A larger study with repeat follow-up assessment to allow for surgical recovery would represent more faithfully the extent of clinical and functional benefit and safety of endobronchial valve insertion. A study has shown that improvement in air trapping increases with time[5] which supports this approach. Currently, there exists an inadequate amount of longer-term safety evidence[18] for the use of endobronchial valves and the scale of our work cannot address this uncertainty in the field. More research in the field is required not least because long-term outcomes of valve insertion are variable and are influenced by a variety of factors, for example, emphysema type.

CONCLUSION:

Endobronchial valve insertion can be used as an effective treatment in patients with advanced heterogenous emphysema who do not achieve satisfactory management using medical and conservative measures. An accurate selection of a suitable subset of endobronchial valve patients is crucial to ensure patients are benefitting from this treatment and that resources are delivered to the most suitable patients. Our analysis suggest that even with fissure completeness patients with a significant paraseptal bullous component of the target lobe may be more at risk of failure of endobronchial valve treatment. This finding differs from an earlier study that suggests the response in patients with giant emphysematous bullae is greater than in patients with heterogenous emphysematous changes.[19]

Additionally, patients with evidence of positive Chartis flow suggestive of collateral ventilation were more likely to demonstrate a negative radiological response following endobronchial valve insertion. Targeting patients with intact fissures and negative collateral ventilation on Chartis data is associated with improved responder rates and supported by studies.[15, 20]

This evaluation highlights that these variables may determine whether endobronchial valve insertion is successful, as demonstrated by radiological response and lung function tests. The study also suggested that A1AT deficiency is may be associated with a lower response rate and will need to be investigated further.

Identifying factors associated with a greater response to endobronchial valve insertion is essential for the appropriate selection of suitable patients to ensure that patients benefit from this treatment. The recommendation from this service evaluation is that endobronchial valve insertion is more likely to be radiologically and clinically successful in patients with intact fissures,

negative collateral ventilation and an absence of a paraseptal bullous component and A1AT; however, more work is needed in this disease category.

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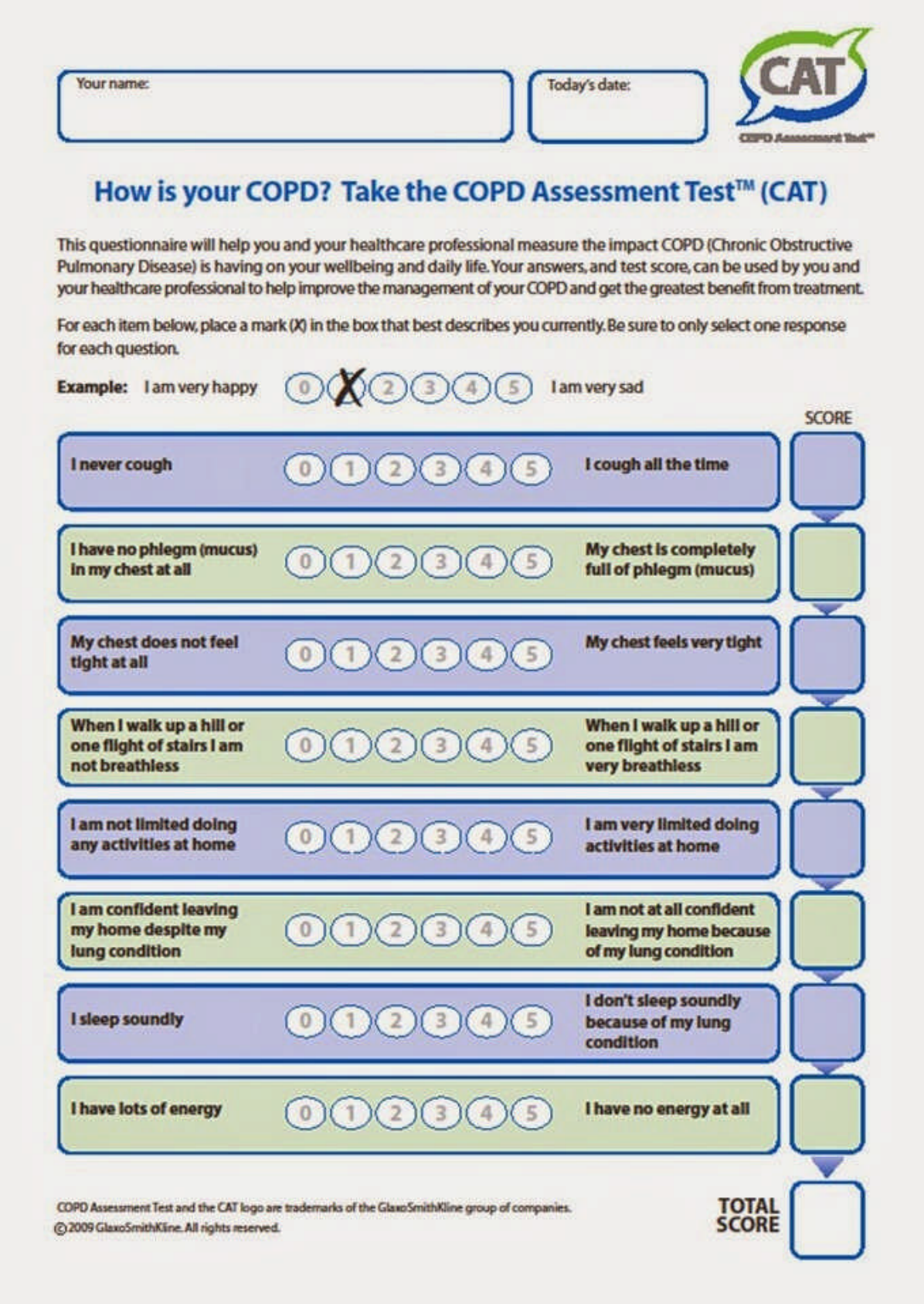
Appendix 1. COPD Assessment Test™ (CAT)



Your name:

Today's date:

CAT
COPD Assessment Test™

How is your COPD? Take the COPD Assessment Test™ (CAT)

This questionnaire will help you and your healthcare professional measure the impact COPD (Chronic Obstructive Pulmonary Disease) is having on your wellbeing and daily life. Your answers, and test score, can be used by you and your healthcare professional to help improve the management of your COPD and get the greatest benefit from treatment.

For each item below, place a mark (X) in the box that best describes you currently. Be sure to only select one response for each question.

Example: I am very happy 0 X 2 3 4 5 I am very sad

			SCORE
I never cough	0 1 2 3 4 5	I cough all the time	
I have no phlegm (mucus) in my chest at all	0 1 2 3 4 5	My chest is completely full of phlegm (mucus)	
My chest does not feel tight at all	0 1 2 3 4 5	My chest feels very tight	
When I walk up a hill or one flight of stairs I am not breathless	0 1 2 3 4 5	When I walk up a hill or one flight of stairs I am very breathless	
I am not limited doing any activities at home	0 1 2 3 4 5	I am very limited doing activities at home	
I am confident leaving my home despite my lung condition	0 1 2 3 4 5	I am not at all confident leaving my home because of my lung condition	
I sleep soundly	0 1 2 3 4 5	I don't sleep soundly because of my lung condition	
I have lots of energy	0 1 2 3 4 5	I have no energy at all	
		TOTAL SCORE	

Appendix 2: mMRC Breathlessness Scale

mMRC breathlessness scale

Grade	Degree of dyspnea
0	no dyspnea except with strenuous exercise
1	dyspnea when walking up an incline or hurrying on the level
2	walks slower than most on the level, or stops after 15 minutes of walking on the level
3	stops after a few minutes of walking on the level
4	with minimal activity such as getting dressed, too dyspneic to leave the house

Appendix 3: Trust MDT Proforma

MDT and Pre-Operative Assessment

Date of the meeting:

Patients' details

Checklist

Smoking cessation	Echocardiogram	P Rehab	V/Q scan	mMRC

Lung function tests:

Test	FEV1	FVC	FEV1/FVC	TLC	RV	RV/TLC	TLco	Kco
Actual								
% predicted								

6 minute walk test

Distance travelled (m)	O2 Saturation (start)	O2 Saturation (end)	O2 Recovery Time

mMRC breathlessness Score

1	2	3	4
Breathless at strenuous Exercise	Breathless walking uphill or upstairs	Breathless at a level grounds at his own pace	Breathless walking within the house

COPD Assessment Test (CAT) score

MDT and Pre-Operative Assessment (cont)

Echocardiogram:

MDT Decision:

MDT members Present:

ASA (1-5)	Anticipated Difficult Airway? (circle)	Is GA contraindicated? (circle)	Is consultant anaesthetist required throughout?
	No	No	YES

Anaesthetic notes:

Intra-Operative Details

Anaesthesia:

Type of Anaesthetic (circle)	Anaesthetic Complications
Sedation Only Sedation then GA GA throughout	

Surgical notes:

Date of Procedure	Operators	Number of valves/coils inserted	Sites of treatment

Free entry including intra operative complications

Length of hospital stay

COPD Assessment Test (CAT) score at discharge

Follow-up assessment

Date of procedure	Date of visit

Complications:

	Pneumothorax-observation	Pneumothorax-aspiration or drainage	COPD exacerbation	Haemoptysis	Pneumonia	Others
Date						

COPD Assessment Test (CAT) score

Lung function tests:

Test	FEV1	FVC	FEV1/FVC	TLC	RV	RV/TLC	TLco	Kco
Actual								
% predicted								

6 minute walk test

Distance travelled (m)	O2 Saturation (start)	O2 Saturation (end)	O2 Recovery Time

mMRC breathlessness Score

1	2	3	4
Breathless at strenuous Exercise	Breathless walking uphill or upstairs	Breathless at a level grounds at his own pace	Breathless walking within the house

Free notes: