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Comparison between the EQ-5D-3L and the SF-6D quality of life (QOL) questionnaires in patients with chronic obstructive pulmonary disease (COPD) undergoing lung volume reduction surgery (LVRS)

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Abstract

Purpose Lung volume reduction surgery (LVRS) has been shown to improve lung function, but also improve the overall quality of life (QOL). The aim of this study is to compare two QOL questionnaires-EuroQol Questionnaire (EQ-5D-3L) and 36-item Short Form Health Survey (SF-36) in patients post-LVRS.

Methods All patients undergoing LVRS for severe chronic obstructive pulmonary disease (COPD) at a single center of excellence were analyzed ($n=94$). Baseline demographic and clinical outcomes were characterized. Both EQ-5D-3L and SF-36 questionnaires were administered to all patients at baseline ($n=94$) and at the end of 1 year ($n=89$) post-surgery. SF-36 was converted to Short Form six-dimensions (SF-6D) using standard algorithm. Correlation, discrimination, responsiveness and differences across the two questionnaires were examined.

Results The mean age of patients enrolled in the cohort was 66 years. There was significant increase in forced expiratory volume (FEV1, 43%), forced vital capacity (FVC 46%), diffusion capacity (DLCO 15%), 6 min walk distance test (6MWD 21%) and a significant decrease in residual volume (RV 23%) at the end of 1-year follow-up. The overall mean utility index significantly improved for both SF-6D and EQ-5D-3L questionnaires at the end of follow-up ($p=0.0001$). However, the magnitude of percentage increase was higher with EQ-5D-3L compared to SF-6D (32% vs. 13%). Stronger correlations confirmed convergent validity at the end of 1-year follow-up between similar domains. Both questionnaires failed to discriminate between different levels of disease severity post-LVRS in patients with severe COPD.

Conclusions Both questionnaires responded similarly in patients with COPD post-LVRS. Combining results from QOL questionnaire(s) along with symptoms of disease and history of exacerbation may be a possible solution for identifying disease severity in old and sick patients unwilling/unable to come to hospital for a pulmonary function test post-LVRS.

Keywords LVRS · QOL · EQ-5D-3L · SF6D

Introduction

Chronic obstructive pulmonary disease (COPD) is the third leading cause of death in the United States [1] and approximately 16 million people reported being diagnosed with COPD [2]. COPD is a debilitating lung condition which includes emphysema and chronic bronchitis. Patients with COPD are more likely to have limitations and difficulty walking and climbing stairs, be unable to go to work, not be involved in social activities, have psychological problems and report poor health status [3]. All these conditions have a major influence on the overall quality of life (QOL) and QOL deteriorates significantly with increasing severity of disease [4].

Depending on the severity of the disease, treatment may include rehabilitation, pharmacotherapy, and/or surgery. Some patients may require lung transplant or lung volume reduction surgery (LVRS). LVRS is more commonly performed in patients with severe upper lobe predominant heterogenous emphysema or in patients with severe non-upper lobe predominant emphysema with low exercise capacity. The surgery is performed using video assisted thoracoscopy,

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a minimally-invasive technique, wherein small incisions are made to assist in inserting a scope to view the lungs and a stapler to remove damaged lung tissue. LVRS not only improves lung function, but it also improves the overall quality of life [5–7].

One of the important considerations of effective treatment is the long-term clinical outcomes. However, assessment of long-term outcomes are sometimes difficult because patients are elderly and sick, and thus are unwilling or unable to travel long distances. Some patients move out of the catchment areas and are lost to follow-up. One way to overcome this problem is to identify an alternative method to assess the clinical outcomes. Quality of life assessment questionnaires have been used as an alternative tool for clinical assessments [8, 9]. Studies have used generic QOL questionnaires-Euro-Qol questionnaire (EQ-5D-3L) and 36-Item Short Form Health Survey (SF-36) to access the QOL in patients with COPD [10–13] and compared them with disease-specific instruments like the St. George's Respiratory questionnaires [14] and have shown that generic questionnaires compared to disease-specific questionnaires do not effectively discriminate between COPD severity levels. But to our knowledge there are no studies comparing QOL questionnaires and their ability to discriminate between levels of disease severity in patients with COPD post-LVRS. Hence the aim of this data analysis is to compare two QOL questionnaires- EQ-5D-3L and SF-36 against levels of disease severity to recommend the best suitable QOL assessment tool for predicting health status in COPD patients post-LVRS.

Methods

Study center and patient population

Data were collected by retrospective reviews of medical records of patients undergoing LVRS for severe COPD at a single center for excellence, at Southern Illinois University School of Medicine (Memorial Medical Center), Springfield IL from December 2006 to October 2015. All patients enrolled in the study underwent LVRS for severe emphysema. The surgery was performed by the same surgeon for all the patients and the procedure was accredited by the Joint Commission in December 2006. The study was approved by the Springfield Committee for Research Involving Human Subjects. As per standard treatment protocol, all patients had to undergo up to 20 supervised sessions of pulmonary rehabilitation over 8–10 weeks prior to surgery. Hence for this study the baseline data were collected post-rehabilitation.

Clinical and baseline data were collected from the electronic medical records of all patients at baseline prior to surgery and during the scheduled 1-year post-surgery follow-up physician visit. All patients who undergo LVRS are required to complete both EQ-5D-3L and SF-36 questionnaires at baseline and at subsequent hospital visits as part of the standard of care. All the enrolled 94 patients completed both the QOL questionnaires at baseline, while only 89 patients completed the 1-year follow-up QOL questionnaires. The remaining five patients were lost to follow-up. Hence for this analysis we included clinical data from 94 patients at baseline and from 89 patients at 1-year follow-up.

Baseline demographic variables

Baseline demographic data including age, gender, race, and work status were collected. Life style information including smoking history, exposure to carcinogens, and disability were recorded at baseline.

Clinical outcomes

At baseline height and weight were measured and body mass index (BMI) calculated using the standard formula. Data on use of oxygen at home, pulmonary function tests including forced expiratory volume (FEV), residual volume (RV), forced vital capacity (FVC), diffusion capacity (DLCO), and total lung capacity (TLC) were collected at baseline and at the end of 1-year follow-up. A 6-min walk distance test (6MWD) was recorded at both the visits.

QOL questionnaire

Both EQ-5D-3L and SF-36 questionnaires were administered to all patients at baseline and at 1 year of follow-up. The EQ-5D-3L questionnaire is a standardized instrument used to measure health related QOL [15, 16]. The instrument consists of five descriptive systems-mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each descriptive system has three possible states (1—"no problem", 2—"some problem", 3—"extreme problem"). The responses for each dimensions were combined to identify the EQ-5D-3L utility index based on the "tariff" calculation methodology reported by Dolan et al. [10, 17]. The SF-36 questionnaire was used to derive a preference-based single utility index Short Form Six-Dimensions (SF-6D) as described earlier by Brazier et al. [10, 18, 19]. The SF-6D utility instrument includes six domains- physical functioning role limitations, social functioning, pain, mental health, and vitality. Each domain has different levels of outcomes. Physical functioning and pain have six possible states, social functioning, mental health and vitality have five possible states and role limitation has only four possible states. For all the domains level 1 represents "no problem".

Statistical analysis

Baseline demographic data are reported as means and standard deviation and frequencies for continuous and categorical variables respectively. Mean with standard deviation was calculated for all the clinical outcomes at baseline and at end of 1-year of follow-up, and percentage change from baseline was calculated. Additionally, effect size was also calculated as (follow-up mean-baseline mean)/baseline standard deviation to provide a measure of the magnitude of change from baseline to follow-up expressed in standard deviation units [20]. The overall QOL index was calculated and compared between baseline and 1-year follow-up for both EQ-5D-3L and SF-6D questionnaires. Changes from baseline to 1 year were tested with the Wilcoxon-signed rank test. Relationships between individual domains of the EQ-5D-3L and SF-6D were assessed using Spearman's correlation (ρ) coefficient for both baseline and 1-year measurements. Any value of $\rho \geq 0.50$ was considered a strong correlation [20]. The discriminative properties of EQ-5D-3L and SF-6D utility indices were compared using receiver operating characteristic (ROC) curves. The area under the ROC curve (AUC) indicated the probability of correctly discriminating between dichotomized groups [11]. In our analysis, the performance of the EQ-5D-3L and SF-6D was evaluated using disease severity. Severity of disease was classified based on the FEV1 and FVC values. Stage 1 "Mild" COPD was defined as FEV1/FVC < 70% and FEV1 ≥ 80% predicted, stage 2 "Moderate" COPD was defined as FEV1/FVC < 70% and 50% ≤ FEV1 < 80% predicted, patients with FEV1/FVC < 70% and 30% ≤ FEV1 < 50% were considered to have stage 3 "severe" COPD while those with FEV1/FVC < 70% and FEV1 < 30% were considered to have Stage 4 "very severe" COPD [21]. The statistical significance of the AUC was tested using the nonparametric approach [22]. The significance level was set as $p < 0.05$ and all analyses were performed using SAS v9.4 (SAS Institute Inc., Cary, NC, USA).

Results

The mean age of patients enrolled in the cohort was 66 years (SD = 7.8). Among 94 patient's in the cohort, 57% were men and 96% were Caucasian. Mean BMI of the cohort was 25 kg/m^2. Sixty-one percent had a smoking history of 60 or more pack-years and none of them were current smokers. Only 19% of the patients were currently working and 80% required regular home oxygen for daily activities. There was significant increase in FEV_1 (43%), FVC (46%), DLCO (15%), 6MWD (21%) and a significant decrease in RV (23%) at the end of 1-year follow-up after LVRS compared to baseline (Table 1). The effect size for FEV_1 (1.29), RV (1.18) and FVC (1.49) reflect substantial change from baseline to follow-up at 1 year.

The overall mean utility index significantly improved for both SF6D and EQ-5D-3L questionnaires, however, both the questionnaires had a medium effect size representing the change from baseline to 1 year (Table 1). The magnitude of percentage increase was higher with EQ-5D-3L-3L compared to SF6D (32% vs. 13%) (Table 1). Both the questionnaires generated similar utility scores, however their distributions were very different (Fig. 1). The EQ-5D-3L utility scores ranged from 0.081 to 0.919 at baseline and from − 0.015 to 0.919 at 1 year of follow-up. While the SF-6D utility scores ranged from 0.403 to 0.927 at baseline and from 0.469 to 0.944 at end of 1 year of follow-up. At the end of follow-up, the utility score was ≥ 0.90 in 36% of the patients with the EQ-5D-3L questionnaire compared to 21% of the patients with SF-6D questionnaire (Fig. 1).

Patients reported significantly reduced problems at 1 year follow-up compared to baseline for all domains in the EQ-5D-3L questionnaire except for the pain/discomfort domain

Table 1 Functional and quality of life outcomes of patients undergoing video assisted thoracoscopic lung volume reduction surgery at baseline and at the end of 1 year of follow-up

Outcome measures	Baseline	1-year	% Change from baseline	Effect size (1 year-baseline)/$SD_{baseline}$
FEV_1 %*	26.7 ± 8.3	37.5 ± 14.7	43.4 ± 48.2	1.29
RV %*	226.2 ± 46.4	171.9 ± 52.6	− 22.6 ± 22.8	− 1.18
FVC %*	65.8 ± 17.0	90.5 ± 20.8	46.4 ± 49.9	1.49
DLCO %*	38.3 ± 12.3	42.7 ± 13.2	15.4 ± 29.2	0.35
TLC %*	133.0 ± 16.4	127.7 ± 18.7	− 3.1 ± 13.8	− 0.31
6MWD*	1147 ± 282	1238 ± 348	20.6 ± 108.3	0.32
EQ-5D-3L utility score*	0.66 ± 0.20	0.77 ± 0.19	31.7 ± 98.1	0.52
SF-6D utility score*	0.66 ± 0.11	0.74 ± 0.14	12.7 ± 22.0	0.64

SD standard deviation, *FEV* forced expiratory volume, *RV* residual volume, *FVC* forced vital capacity, *DLCO* diffusion capacity, *TLC* total lung capacity, *6MWD* 6 min walk distance test, *EQ-5D-3L* EuroQol questionnaire, *SF-6D* Short Form six-dimension health survey

*Significant change at 1-year follow-up from baseline ($p < 0.05$)

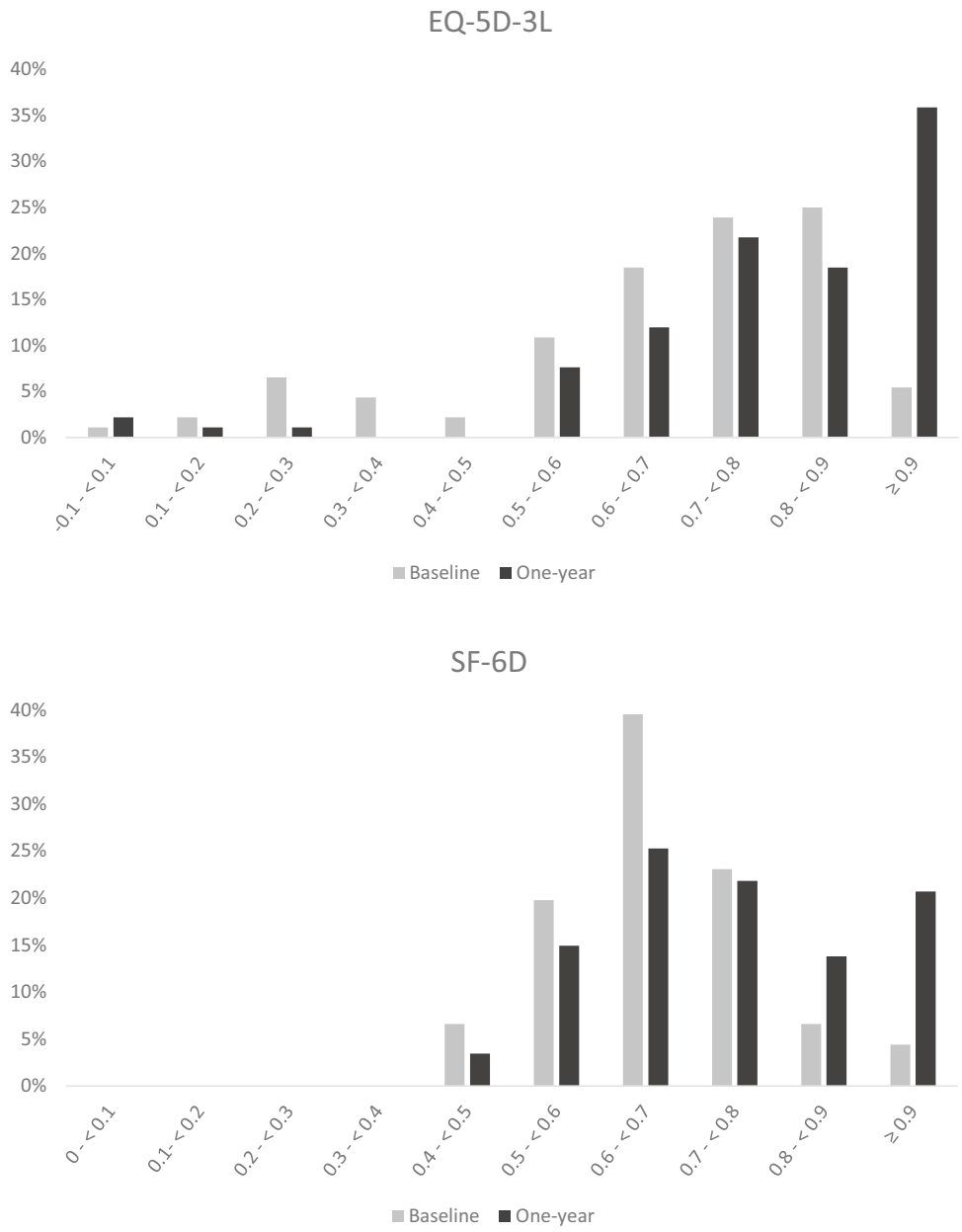

Fig. 1 Histogram of EQ-5D-3L and SF-6D utility scores at baseline and 1-year post-follow-up in patients who underwent video assisted thoracoscopic lung volume reduction surgery

where equal proportion of patient's reported "no problem" at baseline and at the end of 1-year follow-up (67%) (Table 2). With the SF-6D questionnaire significant reduction in problem was reported by patients at 1-year follow-up compared to baseline for role functioning, role limitation, for social functioning, and vitality domains (Table 3). The change in distribution of patients was not statistically significant for pain and mental health (Table 3).

The overall correlation between EQ-5D-3L and SF-6D at baseline and at end of 1-year follow-up was $r=0.64$ and $r=0.75$, respectively. At baseline most of the correlations between the domains of EQ-5D-3L and SF-6D were moderate to weak (Table 4). Although, strong correlations were noted between pain and pain/discomfort ($r=0.54$), and between mental health and anxiety/depression ($r=0.61$). Stronger correlations were observed at 1 year of follow up. The convergent validity was evident at the end of 1-year follow-up between similar dimensions: physical function and mobility ($r=0.51$), physical function and self-care (0.55), Usual activities and role limitation ($r=0.49$), social function ($r=0.52$) and physical function ($r=0.63$), mental health and anxiety/depression ($r=0.45$), and pain and pain/discomfort ($r=0.65$).

One of the selection criteria for performing LVRS is the severity of disease. The discriminative property of both EQ-5D-3L and SF-6D was evaluated based on differentiating disease severity. At baseline 68.1% of subjects presented with very severe COPD, while 30.8% had

Table 2 Distribution of the sample by the EQ-5D-3L at baseline and at 1 year of follow-up in patients who underwent video assisted thoracoscopic lung volume reduction surgery (Wilcoxon-signed rank test comparing change from baseline to follow-up)

Levels	Mobility (%)*	Self-care (%)*	Usual activities (%)*	Pain/discomfort (%)	Anxiety/depression (%)*
At baseline					
No problem	21.5	65.6	8.6	67.0	50.5
Some problem	78.5	34.4	77.4	33.0	45.2
Extreme problem	0	0	14.0	0	4.3
At 1-year follow-up					
No problem	61.3	83.7	50.4	66.7	66.7
Some problem	38.7	16.3	46.2	32.3	31.2
Extreme problem	0	0	3.2	1.1	2.2

*Significant difference in distribution between baseline and 1-year follow-up ($p < 0.05$)

Table 3 Distribution of the sample by the SF-6D at baseline and at 1 year of follow-up in patients who underwent video assisted thoracoscopic lung volume reduction surgery (Wilcoxon-signed rank test comparing change from baseline to follow-up)

Level	Physical functioning (%)*	Role limitation (%)*	Social functioning (%)*	Pain (%)	Mental health (%)	Vitality (%)*
At baseline						
1	0	10.6	30.8	47.9	23.4	1.1
2	0	50.0	28.7	17.0	26.6	7.4
3	11.0	1.1	22.3	16.0	41.5	36.2
4	19.8	38.3	17.0	11.7	4.3	36.2
5	51.6	NA	1.1	4.3	4.3	19.2
6	17.6	NA	NA	3.2	NA	NA
At 1-year follow-up						
1	2.2	40.9	52.1	48.4	28.7	6.4
2	15.7	25.8	31.9	9.7	30.8	25.5
3	37.1	6.4	9.6	22.6	31.9	48.9
4	15.7	26.9	4.3	10.8	4.3	10.6
5	25.8	NA	2.1	7.5	4.3	8.5
6	3.4	NA	NA	1.1	NA	NA

NA not applicable. Number of levels for each domains differ in SF6D. NA denotes those levels that are not available for that domain. For all domains level-1 denotes no problem, Level-6 means severe problem for physical functioning and pain, level-5 means severe problem for social functioning, mental health and vitality; level-4 denotes severe problem for role limitation

*Significant difference in distribution between baseline and 1-year follow-up ($p < 0.05$)

severe and only one subject (1.1%) was classified as having moderate COPD. ROC curves were assessed to determine the level of discrimination between the very severe COPD subjects and those who were not very severe. No significant differences were noted in the areas under the curve when using the EQ-5D-3L utility index (AUC = 0.605) or the SF-6D utility index (AUC = 0.625), $p = 0.7240$. At 1 year 39.3% of subjects were considered to have very severe COPD, while 42.7% had severe COPD and 18.0% were classified as having moderate COPD. ROC curves assessing the level of discrimination between the very severe COPD subjects and those who were not very severe revealed no significant differences between the EQ-5D-3L utility index (AUC = 0.645) and the SF-6D utility index (AUC = 0.661), $p = 0.7100$. The mean utility index was significantly higher in patients without very severe disease compared to those with very severe disease at the end of 1-year, respectively, for both SF-6D (0.77 (SD = 0.14) vs. 0.70 (0.13), $p = 0.0187$) and EQ-5D-3L (0.80 (0.2) vs. 0.75 (0.16), $p = 0.0137$) questionnaires. Additionally, curves were examined to see how the two quality of life indices discriminate between moderate COPD and severe/very severe COPD. No significant differences were noted in the areas under the curve when using the EQ-5D-3L utility index (AUC = 0.644) or the SF-6D utility index (AUC = 0.696), $p = 0.4321$, to distinguish between the moderate and more severe subjects.

Table 4 Spearman's correlation coefficient between different domains at baseline of the QOL questionnaire and at end of 1 year of follow-up in patients who underwent video assisted thoracoscopic lung volume reduction surgery

EQ-5D-3L	SF-6D					
	Physical function	Role limitation	Social function	Pain	Mental health	Vitality
At baseline						
Mobility	0.33*	0.22*	0.34*	0.28*	0.42*	0.11
Self-care	0.48*	0.04	0.25*	0.08	0.06	0.09
Usual activities	0.17	0.07	0.32*	0.33*	0.27*	0.04
Pain/discomfort	− 0.01	0.13	0.25*	**0.54***	0.28*	0.15
Anxiety/depression	− 0.01	0.29*	0.31*	0.38*	**0.61***	0.37*
At 1 year of follow-up						
Mobility	**0.51***	0.41*	0.43*	0.35*	0.36*	0.44*
Self-care	**0.55***	0.37*	0.42*	0.34*	0.20*	0.34*
Usual activities	**0.63***	**0.49***	**0.52***	0.33*	0.41*	**0.50***
Pain/discomfort	0.43*	0.39*	0.38*	**0.65***	0.26*	0.38*
Anxiety/depression	0.45*	0.39*	0.39*	0.38*	0.45*	0.42*

Correlations marked bold indicate strong correlations between similar domains of SF-6D and EQ-5D-3L questionnaires ($\rho \geq 0.50$)

*Significant Correlation between domains ($p < 0.05$)

Discussion

This study examined discrimination, responsiveness, correlation, and differences across EQ-5D-3L and SF-6D questionnaires used to estimate the QOL in patients with COPD post-LVRS. To our knowledge this is the first comparison between the two questionnaires in this group of patients. Both questionnaires were responsive over time and had good correlation across similar domains. Both questionnaires had similar mean utility scores at baseline and at 1-year follow-up and the mean utility scores were higher in patients without very severe disease at 1-year follow-up post-LVRS. However, the percentage change from baseline appeared somewhat higher with the EQ-5D-3L questionnaire.

Several studies comparing these two QOL questionnaires in patients with COPD [10, 11] have demonstrated that EQ-5D-3L and SF-6D do not sufficiently discriminate between COPD severity levels compared to disease-specific QOL instruments [14, 23]. Consistent with the results from these studies our study also demonstrated that both questionnaires do not discriminate between disease severity levels in patients with COPD post-LVRS. Future studies are required to compare the disease severity using both disease-specific QOL questionnaires and generic QOL questionnaires in this group of patients.

There was a significant change in the mean utility scores at 1-year follow-up from baseline with both the questionnaires and the percentage change was higher with EQ-5D-3L questionnaire, however interestingly, the effect size was higher with the SF-6D questionnaire. This reflects the smaller standard deviation at baseline for the SF-6D. The mean utility scores at baseline were similar to data from other studies that calculated the mean utility scores in patients with COPD [24]. Although the overall utility scores were similar between the questionnaires at baseline and end of follow-up, distribution of the utility scores were very different between SF-6D and EQ-5D-3L. The SF-6D scores followed a relatively normal distribution at baseline while the EQ-5D-3L scores were negatively skewed. At the end of 1-year follow-up 36% of the patients were in the highest scoring range (≥ 0.9) with the EQ-5D-3L questionnaire while only 21% were in the highest scoring range for SF-6D questionnaire. Previous studies have demonstrated ceiling effects with EQ-5D-3L questionnaires in patients with chronic disease [11, 13, 25, 26]. Quality of life measures that demonstrate higher ceiling effects may not efficiently differentiate disease severity [27].

The pattern of correlations between domains at the end of 1 year follow-up were similar to previously published studies [10, 25]. Our results confirm the evidence of convergent validity between similar dimensions. In previous studies the usual activity domain of the EQ-5D-3L score had strong correlations with physical function, role limitation and social function domains of the SF-6D questionnaire. In our study the Vitality domain of the SF-6D also had a strong correlation with the usual activity domain of the EQ-5D-3L questionnaire.

The ROC analyses showed that the questionnaires were not effective at differentiating between patients with and without very severe disease. We used pulmonary function test criteria to categorize disease severity. Both the questionnaires failed to discriminate between different levels of disease severity suggesting that neither questionnaire may serve as a proxy to predict health status in patients

with COPD post-LVRS. However, the mean utility scores differed significantly between patients with and without very severe disease and the change in overall utility scores for both SF-6D and EQ-5D-3L questionnaires over time suggests that both the questionnaires may be used as utility tools for capturing the improvement in QOL and in conducting cost-utility analysis.

Lung function tests are required for making a clinical diagnosis, however the current global initiative for chronic obstructive lung disease (GOLD) guidelines recommends a combined assessment of COPD disease severity taking symptoms, lung function test and history of exacerbation into account [23]. From our experience patients who undergo LVRS are old and sick and may not be willing to come to hospital for a follow-up lung function test. Additionally, the results of our study suggests that QOL questionnaires alone may not be sufficient to assess severity of disease in patients with COPD post-LVRS. Hence to capture the severity of disease in patients with COPD post-LVRS, who may be unable to come to the hospital for a lung function test we can consider using the QOL questionnaire(s) in combination with symptoms and history of exacerbations for disease severity assessment.

There are no established methods to compare different QOL questionnaires. We used a combination of four different comparisons—discrimination, responsiveness, correlation, and differences between the two questionnaires as described previously [12, 27, 28]. One of the limitations of this analysis is that the sample size was small and may not be sufficient to correctly discriminate between the disease severity levels. Studies have shown that use of EQ-5D-5L questionnaires with five levels in each dimensions might improve discrimination between different levels of disease severity with a smaller ceiling effect [29, 30]. But our study used the EQ-5D-3L and this may be one of the reasons the QOL questionnaire could not correctly discriminate disease severity levels in patients with COPD post-LVRS.

Conclusions

Both the questionnaires responded similarly in patients with COPD post-LVRS and both questionnaires did not effectively discriminate between levels of disease severity in patients post-LVRS. Combining results from QOL questionnaire(s) along with symptoms of disease and history of exacerbation may be a possible solution for identifying disease severity in old and sick patients unwilling/unable to come to hospital for a pulmonary function test post-LVRS.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Research involving in animal participants This article does not contain any studies with animals performed by any of the authors.

Informed consent Informed consent was obtained from all individual participants included in the study.

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