The impact of endoscopic lung volume reduction on physical activity coaching in patients with severe emphysema

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Shareable abstract (@ERSpublications)
Endoscopic lung volume reduction for patients with severe emphysema is not a prerequisite for physical activity coaching to successfully increase daily physical activities, although it might alleviate patients' experienced difficulties with PA https://bit.ly/3vlrCpp

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Abstract

Introduction Endoscopic lung volume reduction (ELVR) aims to improve pulmonary function in severe emphysema. Physical activity (PA) coaching is expected to improve daily life PA. When improving ventilatory constrains in severe COPD, a better response to PA coaching is expected. The present study investigated the impact of PA coaching in addition to ELVR in severe emphysema.

Methods Patients allocated, based on fissure integrity, in the ELVR or no-ELVR cohort, received the PA coaching intervention with a step counter and smartphone application from 3 to 6 months follow-up. The primary end-point of this research question was the change in daily step count from baseline to 6 months follow-up compared between the ELVR and no-ELVR cohort. The secondary end-points were time spent in moderate to vigorous PA, movement intensity and patient-reported experience with PA between ELVR and no-ELVR.

Results At 6 months, PA in both ELVR+coaching (1479±460 steps·day^{-1}; p=0.001) and no-ELVR +coaching (1910±663 steps·day^{-1}; p=0.004) improved within group, without significant between-group differences (−405±781 steps·day^{-1}; p=0.60). Patients in the ELVR group tended to experience less difficulty with PA compared to no-ELVR+coaching (7±4 points, p=0.08).

Conclusion We found that PA coaching is feasible and can help to enhance PA in patients with severe emphysema. Improving the ventilatory capacity through ELVR is not a prerequisite for a successful coaching intervention to increase objectively measured PA, although it alleviates patients' experienced difficulty with PA in those with severe COPD.

Introduction

Patients with end-stage COPD have severely reduced ventilatory capacity resulting in dyspnoea [1] and decreased daily life activity [2]. In those patients, as in the general population, physical activity (PA) has important health benefits and lowers mortality risk, and should therefore be encouraged as part of the management [1].

Physical inactivity is embedded in the dyspnoea–inactivity vicious circle and is mainly driven by airflow limitation, lung hyperinflation and COPD exacerbations [3]. Different interventions including optimal pharmacotherapy, pulmonary rehabilitation and PA coaching can be offered to alleviate symptoms and improve health. Physical activity coaching interventions were effective in enhancing PA in this patient population [4, 5]. Findings of the PROactive consortium showed a significant effect of a 3-month

telecoaching intervention on PA by using a step counter and a smartphone application which was based on important principles of behaviour change to improve daily life activity [6, 7]. Sub-analyses revealed a smaller effect of the telecoaching intervention in patients with lower exercise capacity and higher dyspnoea scores.

Surgical or endoscopic lung volume reduction (ELVR) is a treatment option for a selected group of symptomatic COPD patients with severe emphysema and hyperinflation. The aim of lung volume reduction is to improve airflow obstruction, decrease hyperinflation and thereby improve ventilatory capacity and symptoms of dyspnoea [8–10]. Becoming less invasive, ELVR has rapidly grown in popularity. By first improving symptoms of dyspnoea and diminishing the burden of being active with ELVR, a better response to PA coaching programmes in improving daily life activity could be expected.

We hypothesise that patients who undergo ELVR followed by a PA coaching intervention will have a larger improvement of daily PA as compared to patients who do not undergo ELVR prior to PA coaching. To investigate this hypothesis, the current study compared the response of adding a 3-month PA coaching programme to patients allocated to an ELVR intervention (ELVR+coaching) *versus* patients not eligible for ELVR (no-ELVR+coaching).

Methods

Subjects

The present study reports a secondary research question embedded in the Belgian Endobronchial Valve Study (BEVA study, NCT03264768) [11]. Patients were enrolled in this study between July 2017 and February 2020. All subjects were screened and discussed at a multidisciplinary emphysema expert meeting (MEET). Subjects meeting the eligibility criteria were invited for the study and signed informed consent. Details on the MEET, inclusion criteria, ELVR intervention and its effectiveness were described elsewhere [11]. In summary, patients with severe heterogeneous emphysema, a 6-min walk distance (6MWD) between 100 and 450 m and modified Medical Research Council (mMRC) score ⩾2 were included in the trial (supplementary table S1). The study was approved by the local Ethical Committee UZ/KU Leuven (study ID s60207).

Design

This is a single centre, prospective interventional cohort trial. Subjects with complete fissure integrity were selected for endoscopic lung volume reduction (ELVR group), subjects with incomplete fissures were allocated to the no-ELVR group. Subject allocation was performed blinded for PA outcomes. All subjects were followed-up for 6 months, and PA coaching was provided in both cohorts after 3 months of follow-up (figure 1).

The study consists of three evaluation moments: 1) baseline visit; 2) intermediate follow-up visit at 3 months (=start of the PA coaching intervention); and 3) final follow-up visit at 6 months (=end of the PA coaching intervention).

Physical activity coaching intervention

The PA coaching intervention was provided for 3 months to all subjects, as part of our emphysema care programme, and started 3 months after group allocation. Subjects were provided with a waist-worn step counter and a project-tailored smartphone application (Linkcare, Barcelona, Spain).

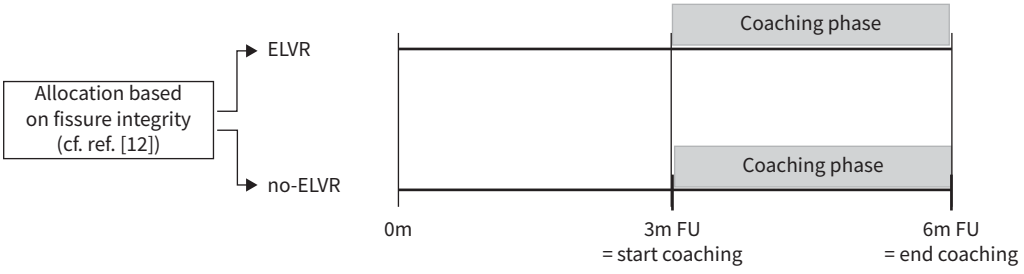

FIGURE 1 Design of the study. ELVR: endoscopic lung volume reduction; 0 m: baseline visit; 3m FU: 3 months follow-up; 6m FU: 6 months follow-up.

An individualised step goal was determined and patients received direct feedback on daily step counts. The patient received daily and weekly feedback on the step goal through the smartphone application. Once a week, subjects were encouraged through the coaching application to increase their daily step goal for the upcoming week. The coach had access to the step count data through an online platform, and phone contacts were set in case the patients did not reach the step goal, did not want to increase the step goal or were not compliant with transferring the step count data to the smartphone application. Detailed information on the PA coaching and its standardisation is described by Demeyer *et al*. [6].

Physical activity outcomes

The primary end-point for this research question was the change in mean daily step count from baseline to 6 months follow-up, objectively measured by the Dynaport MoveMonitor (DAM; McRoberts, The Hague, the Netherlands) [12]. Movement intensity (expressed as $m \cdot s^{-2}$) and time spent in moderate to vigorous intense activities (expressed as minutes per day) were retrieved as secondary end-points. Patients were instructed to wear the DAM on the lower back for seven consecutive days during awake hours, except during washing or bathing. A valid measurement was qualified as at least two weekdays with at least 8 h of wearing time. Weekend days were excluded from the analyses [13].

Patients simultaneously wore an Actigraph GT3X (applied to the same strap) as back-up PA measurement, used for multiple imputation of daily step count in case of failed Dynaport measurement (details described in supplementary material S4 and table S5) [12].

Secondary outcomes

The following outcomes were measured at each clinical visit: 1) patients' reported experience of PA by the clinical visit-PROactive Physical Activity in COPD (C-PPAC) instrument, which captures experienced amount of PA and experienced difficulty with PA [14, 15]; 2) exercise capacity by the best out of two 6-min walk tests (6MWT) according to European Respiratory Society (ERS) American Thoracic Society (ATS) guidelines in a corridor of 50 m [16]; 3) pulmonary function test (including post-bronchodilator spirometry, bodyplethysmography and diffusion capacity) according to ATS/ERS guidelines [17]; and 4) quality of life and symptoms of dyspnoea by the St George's Respiratory Questionnaire (SGRQ) [18] and mMRC dyspnoea scale [19].

Statistics

The Belgian Endobronchial Valve Study was powered on the improvement in post-bronchodilator forced expiratory volume in 1 s (FEV_1) at 3 months [11]. No *a priori* sample size calculation was performed for the PA secondary outcomes.

To test the primary aim of this manuscript (*i.e.* change in main daily step count from baseline to 6 months follow-up between 'ELVR+coaching' *versus* 'no-ELVR+coaching'), between-group differences at 6 months were analysed using mixed model repeated measures analyses, with mean step count as dependent and intervention and visit (both as class variables) as independent variables. We retrieved the intervention*visit interaction effect as main result. Within group changes over time were investigated by separate mixed model repeated measures analyses retrieving the time effect.

A responder analysis was performed for changes in daily step count and C-PPAC using chi-square tests. The minimal important difference (MCID) was set at $1000 \cdot steps \cdot day^{-1}$ for mean step count [20]: at 6 points for the C-PPAC total score and at 4 points for the C-PPAC difficulty and amount sub-score [15].

An association between changes in PA from 0 to 6 months and possible determinants (exercise capacity and pulmonary function) was explored by general linear models (with change in step count from baseline to 6 months follow-up as the dependent variable, and possible determinants categorised according to tertiles as independent variables). The investigated outcomes were: 1) FEV_1, residual volume (RV), RV/total lung capacity (TLC) and 6MWD at 3 months follow-up (*i.e.* before the start of the coaching intervention); and 2) the change between baseline and 3 months follow-up for FEV_1, RV, RV/TLC and 6 MWD. Data of the two cohorts (ELVR and no-ELVR) were pooled to create tertiles. These single exposure models were adjusted for baseline step count.

All statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC, USA). p-value lower than 0.05 was interpreted as statistically significant for all analyses. Data are presented as mean±SD, mean±SEM or proportions. All patients were included in the current analysis, even if they did not complete the 3 months PA coaching programme.

Results

Study population

All patients followed the BEVA study design. Inclusions were stopped when endobronchial valve treatment was reimbursed in Belgium and became part of clinical routine care (February 2020). 56 subjects signed informed consent and 51 patients were allocated (figure 2). Based on Chartis assessment, 28 patients were treated with endobronchial valves and 23 patients were followed-up in the no-ELVR group. PA coaching was provided to all patients. Two patients in the no-ELVR group were not willing to start the coaching, and three subjects in the ELVR group did not complete the coaching intervention. Baseline characteristics of ELVR and no-ELVR cohorts are described in table 1. Patients were very inactive at baseline (mean±SEM for respectively ELVR and no-ELVR: 4178±297 and 4034±399 steps·day^{-1}, p=0.82).

Outcomes on physical activity

PA coaching significantly improved within group daily step count at 6 months in both the ELVR+coaching (1479±460·steps·day^{-1}, p=0.001) and the no-ELVR+coaching group (1910±663·steps·day^{-1}, p=0.004). No differences were observed between groups (−405±781 steps·day^{-1}; p=0.60). Similar observations were made for time spent in moderate to vigorous intense activities (MVPA) and movement intensity at 6 months follow-up (table 2 and figure 3). A trend towards lower C-PPAC score for difficulty with PA was observed favouring ELVR (between-group difference at 6 months 7±4 points in favour of ELVR+coaching, p=0.08) (table 2 and figure 3).

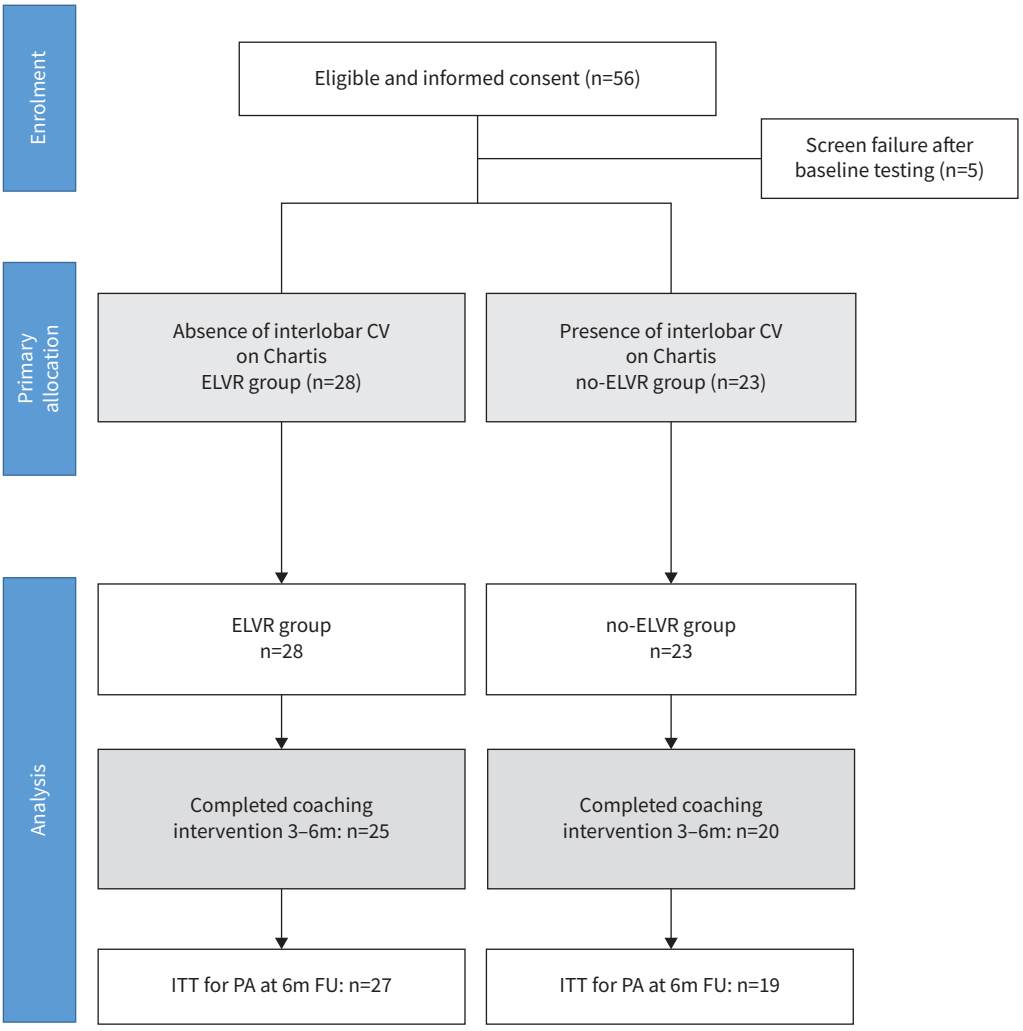

FIGURE 2 Flowchart of the study. ELVR: endoscopic lung volume reduction; CV: collateral ventilation; ITT: intention-to-treat; PA: physical activity, objectively measured; FU: follow-up; m: months.

TABLE 1 Baseline demographics and clinical characteristics, expressed as mean±SD or mean±SEM[#] for endoscopic lung volume reduction (ELVR) group and no-ELVR group; p-values for ELVR *versus* no-ELVR obtained by two-sample t-test and Fisher's exact test

Variable	ELVR group	no-ELVR group	p-value
Subjects n	28	23	
Age years	64±6	62±6	0.21
Sex (% female)	44	61	0.40[¶]
BMI kg·m^{-2}	23±3	22±4	0.34
GOLD stage (% stage IV)	59	48	0.58[¶]
FEV_1 % of predicted	31±7	33±7	0.41
RV % of predicted	223±33	239±49	0.17
RV/TLC	0.67±0.06	0.64±0.09	0.16
D_{LCO} mL·min^{-1}·mmHg^{-1}	2.74±0.67	2.89±0.88	0.50
6MWD m	362±72	377±66	0.45
SGRQ total score	61±10	62±15	0.61
mMRC score %			
2	22	30	0.37[¶]
3	56	61	
4	22	9	
Mean steps·day^{-1}[#]	4178±297	4034±399	0.82
MVPA	63±37	65±26	0.81
Movement intensity	1.60±0.21	1.61±0.22	0.79
C-PPAC total score	53±10	52±14	0.79
C-PPAC amount score	51±14	50±17	0.83
C-PPAC difficulty score	55±9	54±15	0.82

BMI: body mass index; GOLD: Global Initiative for Chronic Obstructive Lung Disease; FEV_1: forced expiratory volume in 1 s; TLC: total lung capacity; D_{LCO}: diffusing capacity of the lung for carbon monoxide; RV: residual volume; 6MWD: 6-min walk distance; SGRQ: Saint George's Respiratory Questionnaire; mMRC: modified Medical Research Council; MVPA: moderate to vigorous intense physical activity; C-PPAC: clinical visit-PROactive Physical activity in COPD instrument. [¶]: Fisher's exact test.

In terms of steps per day, 52% of the patients in the ELVR+coaching and 42% of patients in the no-ELVR +coaching group responded to the coaching intervention (p=0.51 between groups). A significantly higher proportion of subjects reached the predefined MCID for the C-PPAC difficulty score in ELVR+coaching compared to no-ELVR+coaching at 6 months (response rate 67% *versus* 29%, respectively, p=0.02).

TABLE 2 Changes for objectively measured physical activity (PA) and patient's perception of PA between endoscopic lung volume reduction (ELVR) *versus* no-ELVR at 6 months follow-up (between-group differences) and within-group changes at 3 and 6 months in both groups

		Within-group difference 3 months	Within-group difference 6 months	Between-group difference 6 months	Between-group p-value
Mean daily steps day^{-1}	ELVR	545±465	1479±460[#]	−404±781	0.60
	no-ELVR	−23±679	1910±663[#]		
MVPA min·day^{-1}	ELVR	7±8	15±7[#]	−3.22±10	0.76
	no-ELVR	−0.7±9	18±7[#]		
Movement intensity m·s^{-2}	ELVR	0.02±0.03	0.05±0.03	−0.07±0.05	0.20
	no-ELVR	0.03±0.05	0.11±0.04[#]		
C-PPAC difficulty score (points)	ELVR	11±3[#]	11±3[#]	7.20±4.10	0.08
	no-ELVR	−0.7±3	3±2		
C-PPAC amount score (points)	ELVR	3±4	8±4[#]	0.74±5.17	0.89
	no-ELVR	−0.1±4	6±3		
C-PPAC total score (points)	ELVR	7±3[#]	9±3[#]	4.23±3.91	0.28
	no-ELVR	−2±2	4±2		

Data expressed as mean±SEM. MVPA: moderate to vigorous intense physical activity; C-PPAC: clinical visit-PROactive Physical activity in COPD instrument. [#]: p-value of within-group difference <0.05.

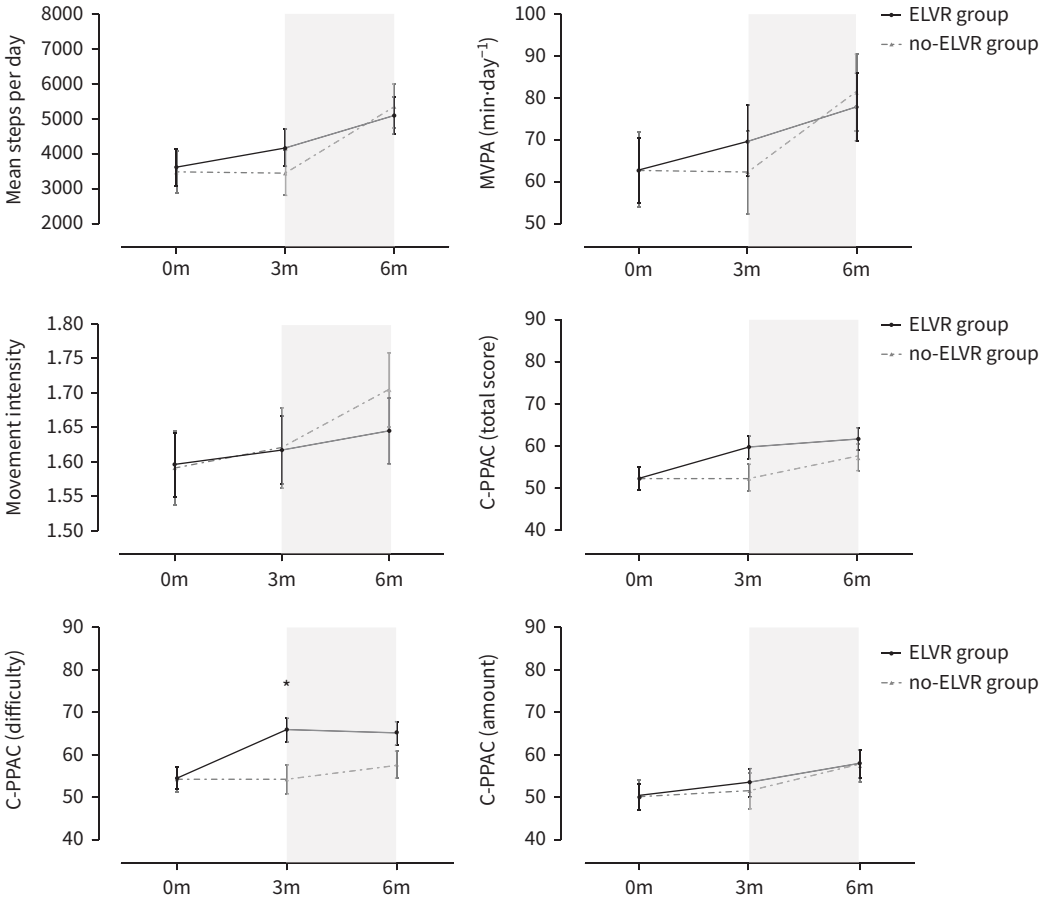

FIGURE 3 Mean±SEM for objectively measured physical activity (PA) and patient-reported experience of PA in patients with endoscopic lung volume reduction (ELVR, solid line) and no-ELVR (dotted line) at baseline, 3 months (3m) and 6 months (6m) post allocation. Physical activity coaching was provided in both groups between 3 and 6 months follow-up; indicated by light-grey bar. *: significant between-group differences for ELVR *versus* no-ELVR. MVPA: moderate to vigorous intense physical activity; C-PPAC: clinical visit-PROactive Physical activity in COPD instrument.

Exploratory analysis: determinants of successful PA coaching intervention

Figure 4 shows the determinants for successful coaching. Better FEV_1 (p=0.06) and less hyperinflation (*i.e.* reduced RV/TLC) (p=0.04) tended to be associated with a better response to coaching, but RV and 6MWD at 3 months were not (p=0.32 and p=0.45, respectively). Changes in FEV_1, RV, RV/TLC ratio and 6MWD (0–3 months) were not related to coaching response (p>0.05 for all).

Discussion

This study shows that PA can be improved in patients with severe emphysema using PA coaching, regardless of undergoing ELVR or not. Current data do not confirm our hypothesis that improved dyspnoea and better function after ELVR yields a better response in PA coaching compared to more symptomatic or more ventilatory-limited patients without ELVR. Patients in the ELVR group did experience less difficulty with PA compared to patients without ELVR.

This research illustrates that the PA coaching intervention is feasible and may help to improve PA, even in patients with severe COPD. In contrast to our initial hypothesis, our findings demonstrate that clinically significant improvements by lung volume reduction are no prerequisite for a successful PA coaching programme. Nevertheless, our exploratory analysis on determinants of change in PA suggests that the PA coaching benefits may be larger in patients with a better lung function at the start of the coaching intervention. These findings corroborate with earlier studies [6] and are to some extent confirmed by the Physacto study where an increase in PA was also achieved in the group treated with a placebo

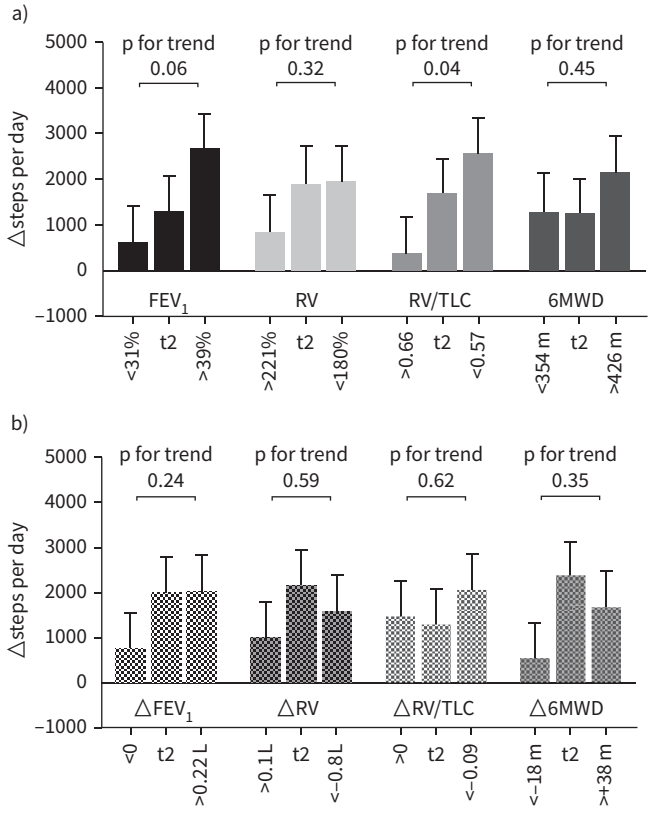

FIGURE 4 Association between lung function (FEV_1, RV, RV/TLC), exercise capacity (6 MWD) obtained at 3 months follow-up and change in physical activity over 6 months. Pooled data from ELVR and no-ELVR categorised in tertiles (t1, t2, t3) from worse to better. a) Determinants at 3 months follow-up; b) change in determinants between baseline and 3 months follow-up. Range and sample size per tertile for all outcome measures are displayed in supplementary table S3. FEV_1: forced expiratory volume in 1 s; RV: residual volume; TLC: total lung capacity; 6MWD: 6-min walk distance.

bronchodilator [21]. Of note, the patients in "Physacto" had substantially more ventilatory reserve compared to our patient group.

A trend towards significant difference between the ELVR and no-ELVR group was found in C-PPAC score for experienced difficulty with PA at 6 months. Patients undergoing ELVR+coaching were 2.3 times (95% CI: 1.13–5.2) more likely to improve experienced difficulty with PA compared to usual care without ELVR. This finding suggests that ELVR tends to alleviate difficulties during daily life activities. Again, these data are in line with the Physacto trial in which the addition of bronchodilator therapy to behavioural intervention could not further improve the objectively measured daily life activity but did significantly affect the perceived difficulty with PA [21]. Interventions such as bronchodilator therapy or ELVR can both improve experienced difficulty with PA. It is tempting to speculate that this improvement is important to maintain daily life activities on the long term or to slow down the expected decline in PA. This still needs to be confirmed with long-term follow-up data.

Additionally, our data show that ELVR as stand-alone intervention is not enough to significantly change daily life activities in patients with end-stage COPD. ELVR provides physiological improvements to patients with severe emphysema, but this results in only limited natural recovery of PA outcomes 3 months after the intervention. This is in contrast to the results of Hartman *et al.* [22] showing a significant improvement of 1252±1468 mean steps·day^{-1} 6 months post ELVR without any additional intervention. Baseline characteristics for lung function, exercise capacity and PA were comparable between both studies, but it is difficult to address if a difference in encouragement or education about PA can explain these findings.

Strengths and limitations

This study design allows us to investigate how important improvements in ventilatory constrains and functional capacity determine the response to PA coaching. By including objectively measured PA as well as subjectively measured patients' perception on daily life activities, we provide a holistic exploration of physical activity. With a complex study design and no randomisation, we have to recognise a number of limitations. First, as this pre-planned study was part of a larger trial at University Hospitals Leuven (BEVA study), the original sample size calculation was powered for change in FEV_1 at 3 months follow-up, and not powered for objectively measured PA. However, a convenient sample size in both the ELVR and no-ELVR group was achieved. Second, in our study, PA coaching was offered after 3 months post intervention; however, the ideal timing of this intervention after ELVR is still a matter of debate. As PA coaching was implemented between 3 and 6 months follow-up, the observed benefits on PA may still relate to the long-term benefits of the ELVR intervention. The observation of PA improvements in the no-ELVR group occurring when coaching was implemented, however, is indicative of the power of such a behavioural intervention. Finally, patients included in this experimental study were highly motivated and compliant, which might not be representative for the complete COPD population. This could have had an impact on the PA coaching programme.

Conclusion

PA coaching is feasible and can help to enhance PA in patients with severe emphysema. Improving the ventilatory capacity through lung volume reduction is not a prerequisite for successful PA coaching in patients with severe emphysema, although it alleviates patients' experienced difficulties with PA.

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Provenance: Submitted article, peer reviewed.

This study is registered at www.clinicaltrials.gov with identifier number NCT03264768.

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Conflict of interest: A. Blondeel has nothing to disclose. H. Demeyer has nothing to disclose. L.J. Ceulemans has nothing to disclose. J. Coolen has nothing to disclose. S. Everaerts has nothing to disclose. H. Geysen has nothing to disclose. G.M. Verleden has nothing to disclose. D. Van Raemdonck has nothing to disclose. C. Dooms has nothing to disclose. T. Troosters has nothing to disclose. W. Janssens reports a grant from PulmonX (for the endobronchial valves), and grants from AstraZeneca and Chiesi, outside the submitted work. Wim Janssens is co-founder of ArtiQ, a KU Leuven spin-off company in respiratory diseases.

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