Size-matching in lung transplantation by computed tomography for end-stage interstitial disease: a retrospective analysis

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Background: Size matching between donors and recipients is a major issue in lung transplantation (LTx), especially in patients with restrictive lung disease (RLD). This study aims to evaluate computed tomography (CT) as an additional method for defining the total lung capacity (TLC) in patients with end-stage interstitial disease awaiting LTx.

Methods: Clinical data and CT scans from patients who underwent a first LTx from January 2014 to July 2018 in Bichat Hospital, Paris, were prospectively included in a database. CT TLC (ctTLC) was retrospectively calculated after semi-automatic contouring of the parenchyma and compared with measured TLC (mTLC) and predicted TLC (pTLC) values.

Results: The study group included 89 patients (male:female =68:21; mean age, 59.5±10.0 years). The time between pulmonary function tests (PFTs) and CT scan was 162±270 days [median, 67 days; interquartile range (IQR), 0–233 days]. ctTLC was inferior to mTLC and pTLC (respectively 2,979±1,001 mL, 3,530±1,077 and 6,381±955 mL, P<0.001). The relative difference between CT lung volume (ctLV) and measured lung volume (mLV) was higher on the left than on the right side (25.4% *vs.* 16.3%, respectively, P=0.11). After exclusion of two outliers, we found a significant correlation between ctTLC and mTLC (r=0.762, P<0.001).

Conclusions: CT volume is a feasible method to assess TLC in patients with end-stage interstitial disease awaiting LTx. This study highlights potential size-mismatch for graft selection before LTx and opens the perspective of a prospective trial evaluating impact of size-matching by donor-recipient (D-R) ctTLC ratio on postoperative outcomes.

Keywords: Lung transplantation (LTx); interstitial lung disease (ILD); total lung capacity (TLC); computed tomography scan (CT scan)

Introduction

Lung transplantation (LTx) is a life-saving option for selected patients with end-stage interstitial lung disease (ILD), but the choice of adequate grafts has long been debated. According to the recommendations from the International Society of Heart and Lung Transplantation (ISHLT), the very rapid evolution of certain clinical forms has led teams to list patients more quickly (1). The size mismatch between donor and recipient total lung capacity (TLC) is a poor prognostic factor of lung function and survival after LTx, and a frequent restriction to graft acceptance (2,3).

In this setting, the definition of the appropriate graft size and the optimal method for defining it remains controversial. Chest diameter, chest X-ray, anthropometry, weight, and other factors have been used to predict lung volume (4,5). Predicted TLC (pTLC) using size and sex as independent variables, and measured TLC (mTLC) using plethysmography are used by most teams to match lung sizes (6,7). The limitations of these tools are well known and perioperative complications related to size mismatch remain and directly impact survival after LTx (8,9).

The recent development of computed tomography (CT) and image processing technologies makes it possible to accurately measure the volume of each lung (10-12). Some teams are already using this value as a reference for choosing the size of lung grafts (13), but no study has been specifically dedicated to ILD. The purpose of this work is to study the feasibility of using CT TLC (ctTLC) and to determine the correlation between ctTLC, mTLC, and pTLC in patients with end-stage ILD awaiting LTx. We present this article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1586/rc).

Methods

Study design

Medical records from patients who underwent LTx in Bichat University Hospital, Paris, France, were prospectively included in a local database. Characteristics of patients who underwent a first LTx for ILD between January 2014 and July 2018 were then retrospectively analyzed. ILD patients were defined by pre-transplantation pulmonary function test (PFT) showing a restrictive physiology, based on either an mTLC <80% predicted or a forced expiratory volume in 1 second (FEV1)/forced vital capacity (FVC) ratio >0.85 with a FEV1/FVC ratio >0.85 with a FVC <80% predicted (in the absence of TLC measurement) (14). Volumes of right and left lungs were calculated on the latest pre-transplantation CT scan to obtain ctTLC, and compare it to the latest pre-transplantation mTLC and pTLC. All patients signed an informed consent to authorize prospective data collection and retrospective data analysis. The database was declared to the French Commission for Informatics and Freedom [Commission National Informatique et Liberté (CNIL)] (authorization 1866407v0). The study of patients' outcome was approved by the Regional Committee for Person Protection [Comité de Protection des Personnes-Ile de Franc, (CPP-IDF2)] (EudraCT/IRB 2017-A01714-49). The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Primary endpoint is the correlation between ctTLC, mTLC, and pTLC in patients with end-stage ILD awaiting LTx.

PFTs

The PFTs were performed at the time of listing. TLC was measured by plethysmography, using a 2003 Jaeger® Masterscreen™ Body Diffusion device (The Surgical Company, Amsterdam, The Netherlands). FEV1, functional residual capacity and FVC were measured by spirometry using a 2015 Jaeger® Vyntus™ Master device (The Surgical Company). PFT lung volumes for each lung was calculated by using perfusion scintigraphy: in patients

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Highlight box

Key findings

- We observed a strong correlation between computed tomography (CT) total lung capacity (TLC) (ctTLC) and measured TLC (mTLC) (Pearson r=0.762 with P<0.001) with the following regression equation: ctTLC (mL) = 0.6761 × mTLC (mL) + 460.

What is known and what is new?

- Size matching between donors and recipients is a major issue in lung transplantation, especially in patients with restrictive lung disease (RLD).
- CT-derived lung volumes correlate with TLC better than predicted TLC in patients with RLD.

What is the implication and what should change now?

- CT determination of TLC and respective volumes of the right and left lung is feasible in patients with end-staged interstitial lung disease awaiting transplantation and may be an interesting lead to choose the size of lung grafts.

Table 1 Study group (n=89)

Demographic parameters	Values
Male	68 (76.4)
Age (years)	59.5±10.0
Height (cm)	171±8
Weight (kg)	75±15
BMI (kg/m^2)	25.7±4.76
Diagnosis	
IPF	49 (55.1)
Connective tissue disease-associated	18 (20.2)
Hypersensitivity pneumonitis	7 (7.9)
Pneumoconiosis	6 (6.7)
Other	9 (10.1)
Surgical history	17 (19.1)
Lung biopsy	12 (13.5)
Tube thoracostomy/pneumothorax	2 (2.2)
Pleurectomy/pneumothorax	1 (1.1)
Talc pleurodesis/pneumothorax	1 (1.1)
Childhood sarcoma metastasectomy	1 (1.1)
High emergency LTx	16 (18.0)
Single LTx	43 (48.3)

Values are presented as n (%) or mean ± SD. BMI, body mass index; IPF, idiopathic pulmonary fibrosis; LTx, lung transplantation; SD, standard deviation.

without pulmonary embolism, it is a reliable exam to assess each lung volume as it is recommended also to predict post-operative lung function in lung cancer patients undergoing pneumonectomy (15). Calculation of pTLC was carried out using the European Respiratory Society formulas defined in 1995 (5): for men: pTLC (mL) = (7.99 × H – 7.08) × 1,000, and for women: pTLC (mL) = (6.60 × H – 5.79) × 1,000, with H = height (m). The statistical analysis was done in 2020, before the publication by the ERS of the new global lung initiative TLC equations in 2021 (16). Measured and predicted right and left lung volumes [measured right lung volume (mRLV), predicted RLV (pRLV), measured left lung volume (mLLV), and predicted LLV (pLLV), respectively] were calculated from the TLC weighted by the results of lung perfusion scan.

CT volume analysis

CTs were performed on Aquilion ONE GENESIS 320 rows CT, Canon Medical system, Otawara, Japan. Parenchymal slides from the last CT before LTx were analyzed with CT Lung Density Analysis software (Vitrea Advanced Visualization software, Vital Images, Minnetonka, MN, USA). Lung volumes were calculated after semi-automatic contouring of the parenchyma. Interval chosen between each cut was 5 mm. Several measurements were performed by including and then excluding unventilated sub-pleural fibrosis areas. The surfaces were manually adjusted in the frontal and sagittal planes. Average densities and total volume of the parenchyma thus determined were calculated by the software (Figure S1).

Statistical analysis

Continuous variables with normal distribution were reported as mean and standard deviation, and compared using Student t-test. Continuous variables with non-normal distribution were reported as mean, median and interquartile range (IQR) and compared using Mann-Whitney test. Categorical variables were reported as count and proportion, and compared using Fisher or chi-squared tests when appropriate. Overall survival was defined as the time interval between the date of operation and the date of death or the last follow-up visit for censored patients. Follow-up information was obtained from the hospital case records. Median time of follow-up for the study group was 458 days (IQR, 199–948 days). Actuarial survival curves were estimated by the Kaplan-Meier method. Correlations were performed using Pearson and Spearman determination of the r coefficient in normal and non-normal variables, respectively. All data analyses were conducted with two-sided test. A P value <0.05 was considered significant. Statistical analyses were conducted using the Prism software (GraphPad Prism version 7.00, La Jolla, CA, USA).

Results

Study group

A total of 89 patients (male:female =68:21; mean age, 59.5±10.0 years) were included in the study. Demographic characteristics are summarized in *Table 1*. Histological diagnoses were grouped into four main groups following

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Table 2 PFTs (study group, n=89)

PFT parameters	Values
FEV1 (mL)	1,687±600
FEV1 (%)	54±17
FVC (mL)	1,991±780
FVC (%)	52±18
VC (mL)	2,088±837
VC (%)	52±18
RV (mL)	1,414±485
RV (%)	66±22
FRC (mL)	2,132±681
FRC (%)	65±17
TLC (mL)	3,530±1,077
pTLC (mL)	6,381±955
TLC (%)	75

Values are presented as mean ± SD or %. PFT, pulmonary function test; FEV1, forced expiratory volume in 1 second; FVC, forced vital capacity; VC, vital capacity; RV, residual volume; FRC, functional residual capacity; TLC, total lung capacity; pTLC, predicted total lung capacity; SD, standard deviation.

Table 3 CT measurements of lung volume and density (study group, n=89)

Parameters	Values
Lung volume (mL)	
Right lung	
Ventilated volume	1,363±593
Total volume	1,540±516
Left lung	
Ventilated volume of left lung	1,188±592
Total volume of left lung	1,339±554/ 1,291 [957–1,609]
ctTLC	2,880±989
Lung density (HU)	
Right lung	
Ventilated mean density	−601±86
Ventilated standard deviation of density	−315±48
Whole mean density	−556±111
Whole standard deviation of density	−336±48
Left lung	
Mean density of ventilated left lung	−593±107
Ventilated standard deviation of density	−309±46
Mean density of whole left lung	−553±126
Whole standard deviation of density	−329±48

Values are presented as mean ± SD or median [interquartile range]. CT, computed tomography; ctTLC, computed tomography total lung capacity; HU, Hounsfield unit; SD, standard deviation.

multidisciplinary discussion and pathological examination of native lungs. Idiopathic pulmonary fibrosis (IPF) was the most common diagnosis found with 55% (n=49) of cases. Among the nine cases with "other" diagnosis, there were three sarcoidosis, three unclassifiable fibrosis, two non-specific interstitial pneumonia, and one desquamative interstitial pneumonia. None of the patients had a history of major lung resection. Double LTx was performed in 46 patients (51.7%), and high emergency LTx in 11 patients (12.4%). Of the 43 patients who received a single LTx, 31 were transplanted on the right side (72.1%). After a mean follow-up of 583±483 days, 3-year survival was 61% (Figure S2).

PFT

Plethismographic and spirometric data are summarized in *Table 2*, with a mean mTLC value of 3,530±1,077 mL. Perfusion scan found a mean perfusion of 52%±17% on the right side. The average time between the PFT and CT and between PFT and transplantation was respectively 162±270 days (median, 67 days; IQR, 0–233 days) and 295±286 days (median, 218 days; IQR, 127–377 days).

CT measurements

The data from the CT analysis are summarized in *Table 3*. The ctTLC could be measured in all patients, with an average of 2,880±989 mL. The average difference between total and ventilated volumes on the scanner was 329±323 mL. CT volumes of the right lung exhibited a normal distribution (D'Agostino and Pearson normality test, P=0.16) while CT volumes of the left lung did not (P=0.005). Statistical analysis revealed a significant difference between CT volume of the right and left lung (P<0.001, *Figure 1*). There was no significant difference between the average right and left densities [−556±111 *vs.* −553±126 Hounsfield unit (HU)].
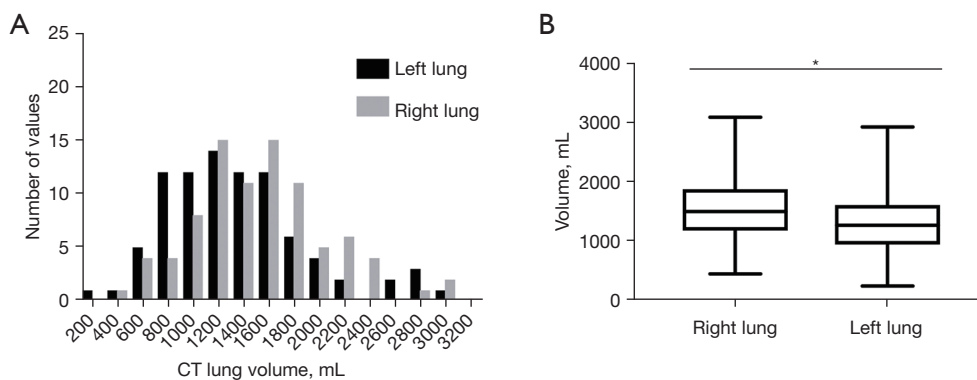
Figure 1 Frequency distribution of CT volume of the right lung and left lung. *, P<0.001. CT, computed tomography.
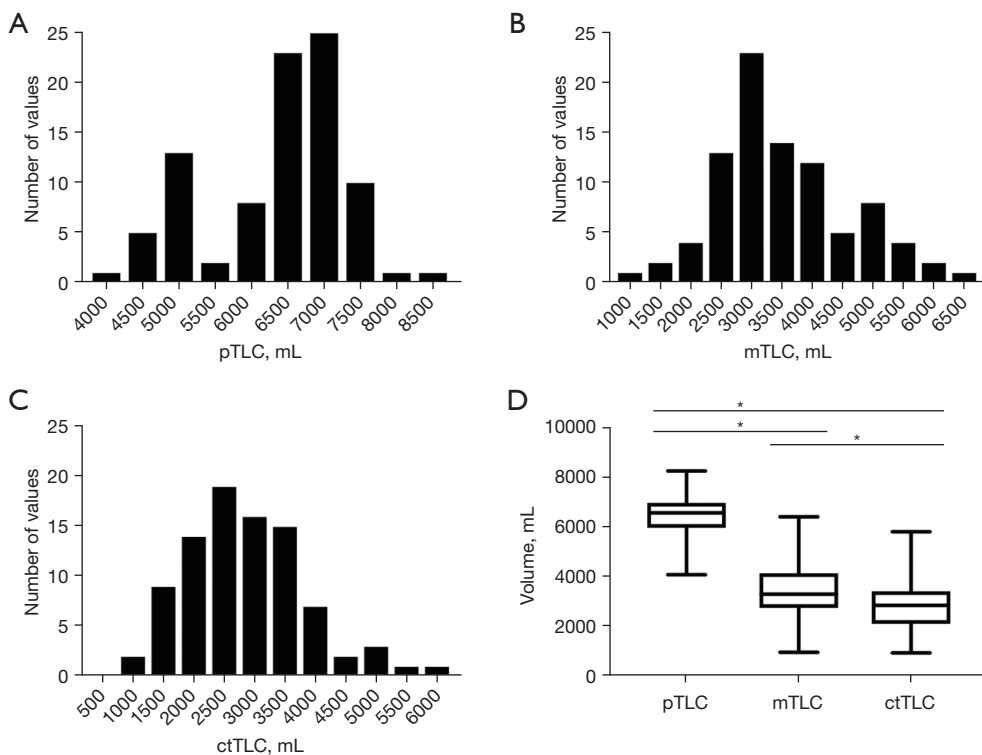

Figure 2 Frequency distribution of pTLC, mTLC, and ctTLC. *, P<0.001. pTLC, predicted total lung capacity; mTLC, measured total lung capacity; ctTLC, computed tomography total lung capacity.

Comparison of pTLC, mTLC, and ctTLC

mTLC and ctTLC exhibited a normal distribution (P=0.23, P=0.054, respectively), while pTLC did not (P=0.02). CtTLC was significantly lower than mTLC and pTLC in three-variable comparison (Friedman test for paired measures, P<0.001) and in two-variable comparisons (Wilcoxon matched-pairs signed rank test, P<0.001 for all comparisons, *Figure 2*).

Assessment of right and left lung volume

We analyzed the respective volumes of the right and left lung according to the three modalities (*Figure 3, Table 4*). There was a more important difference between predicted lung volume, measured lung volume (mLV), and CT lung
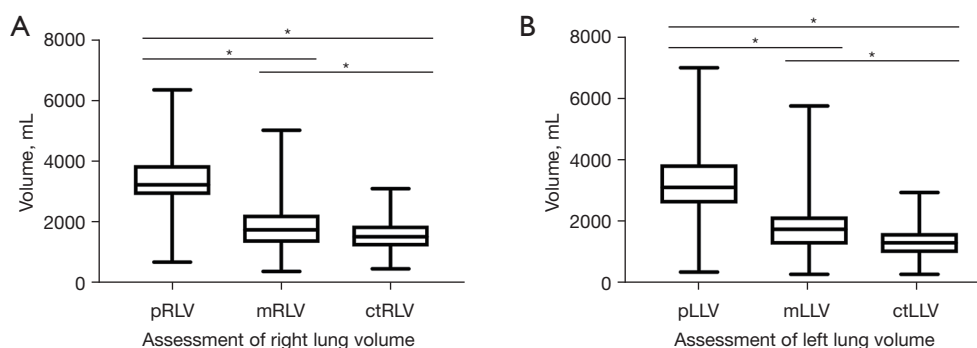
Figure 3 Three-modality assessment of right and left lung volume. *, P<0.001. pRLV, predicted right lung volume; mRLV, measured right lung volume; ctRLV, computed tomography right lung volume; pLLV, predicted left lung volume; mLLV, measured left lung volume; ctLLV, computed tomography left lung volume.

Table 4 Difference in the assessment of right and left lung volume according to the modality considered (study group, n=89)

Lung volumes	Right lung	Left lung
mLV *vs.* pLV		
Median (mL)	−1,432	−1,388
P value	<0.001	<0.001
ctLV *vs.* pLV		
Median (mL)	−1,664	−1,899
P value	<0.001	<0.001
ctLV *vs.* mLV		
Median (mL)	−260	−351
Mean ± SD (mL)	−301±653	−457±767
95% CI	−439 to −164	−619 to −296
Relative difference (%)	16.3	25.4
P value	<0.001	<0.001

Relative difference = (mean ctLV − mean mLV)/mean mLV. mLV, measured lung volume; pLV, predicted lung volume; ctLV, computed tomography lung volume; SD, standard deviation; CI, confidence interval.

volume (ctLV) on the left side than on the right side.

Correlations between pTLC, mTLC, and ctTLC

Results of correlation and linear regression analyses are presented in *Figure 4*. We first analyzed raw data and found a weak correlation between all continuous variables (ctTLC *vs.* mTLC: Pearson r=0.466 with P<0.001; ctRLV *vs.* mRLV:

Spearman r=0.483 with P<0.001; ctLLV *vs.* mLLV: Spearman r=0.499 with P<0.001) (*Figure 4A*). After exclusion of two outliers on CT measurements (one bilateral pneumothorax listed in high emergency, one emphysema of upper lobes as histological comorbidity), we observed a strong correlation between ctTLC and mTLC (Pearson r=0.762 with P<0.001) with the following regression equation: ctTLC (mL) = 0.6761 mTLC (mL) + 460 (*Figure 4B*). The agreement between the two measurements are provided in Figure S3.

Discussion

Main result reminder

In our study, we found a significant difference between each of the three modalities studied for assessing TLC. Thus, average ctTLC was lower than the mTLC and much lower than the pTLC. Significant differences were also observed according to pulmonary side: the left lung CT volume was significantly lower than that of the right lung. Differences between the volumes measured on CT and those measured on PFT was greater on the left side. Analysis of the correlations between the different TLC measures revealed a strong correlation between mTLC and ctTLC. This confirms the findings of a previous study which showed that CT-derived lung volumes correlate with TLC better than pTLC in patients with restrictive lung disease (RLD) (17). It could be a potential surrogate marker for size matching in LTx.

The impact of graft sizing

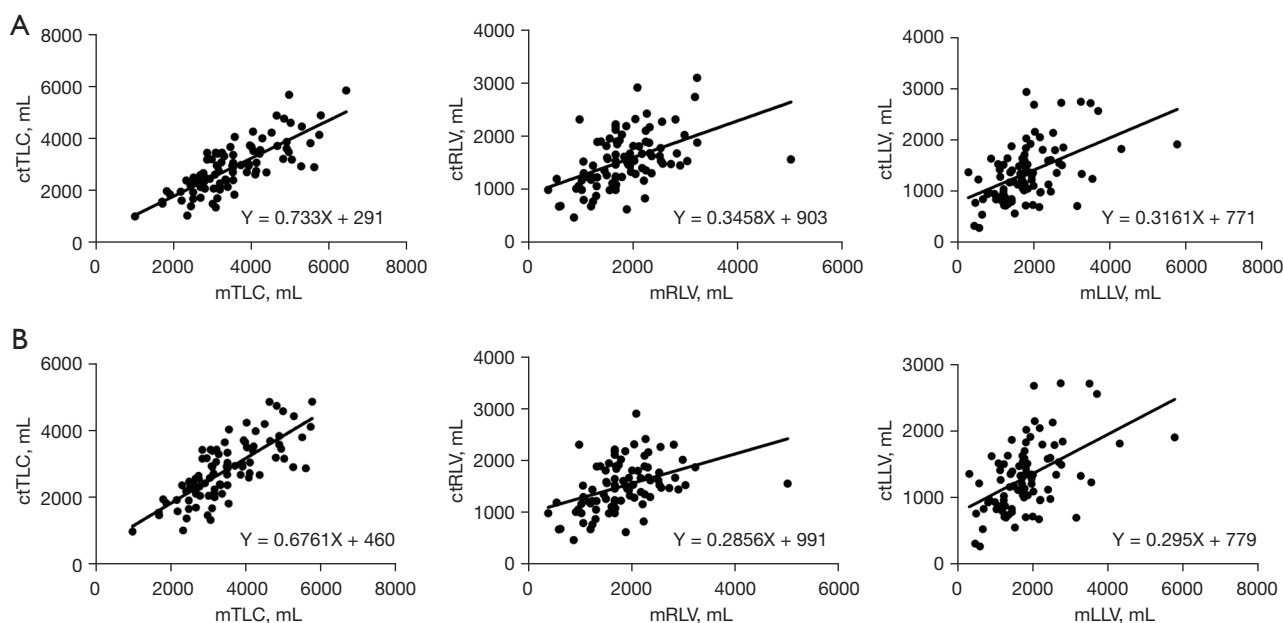Size of grafts in single or double LTx is decisive for both

Figure 4 Linear regression of ctTLC according to mTLC for both lungs together and separately. (A) All patients, n=89. ctTLC *vs.* mTLC: Pearson r=0.466 with P<0.001; ctRLV *vs.* mRLV: Pearson r=0.483 with P<0.001; ctLLV *vs.* mLLV: Pearson r=0.499 with P<0.001. (B) After exclusion of two outliers on CT measurements (one pneumothorax, one emphysema of upper lobes), n=87. ctTLC *vs.* mTLC: Pearson r=0.762 with P<0.001; ctRLV *vs.* mRLV: Pearson r=0.4189 with P<0.001; ctLLV *vs.* mLLV: Pearson r=0.503 with P<0.001. ctTLC, computed tomography total lung capacity; mTLC, measured total lung capacity; ctRLV, computed tomography right lung volume; mRLV, measured right lung volume; ctLLV, computed tomography left lung volume; mLLV, measured left lung volume.

short-term and long-term outcomes (2). When implanted organ is oversized, surgical difficulties encountered may result in need of achieving a lung-volume reduction with the risk of prolonged air leaks, pulmonary atelectasis, pneumopathy, hemodynamic failures at chest closure, and even decreased survival (9). On the other hand, undersized grafts expose to risks of empyema, acute respiratory distress syndrome with weaning difficulties from mechanical ventilation and primary graft dysfunction (PGD), especially after single LTx (3). In addition to more complicated postoperative outcomes, size-mismatch has a negative impact on long-term survival. If all series report an excess mortality in case of undersizing, effects of oversizing are more discussed. Eberlein *et al.* described a beneficial effect of oversizing that reduces complications such as PGD (18). However, these results are obtained from series of patients with heterogeneous pathologies [chronic obstructive pulmonary disease (COPD), emphysema, fibrosis, etc.] and procedures (single and double lung transplants): oversizing is limited by the capacity of rib cage to contain the grafts and the necessity to close the chest at the end of surgery. In restricted pathologies, Riddell *et al.* found an overall

survival and a chronic lung allograft dysfunction (CLAD)-free survival significantly improved following a size-matched double LTx, compared to those with donor-recipient (D-R) pTLC ratio <0.8 or >1.2. But for single LTx, size-matching based on a D-R pTLC ratio >0.8 and <1.0 did not significantly improve survival (19): the authors report non-significant trends towards improvement in grade 3 PGD and post-LTx survival.

Definition of graft sizing

In most teams, pTLC is used to adapt the size of the graft. Calculation of this value is based on equations whose only variables are sex and height. Adapted for healthy European individuals, this tool is much less suitable for predicting lung volumes in patients with fibrosis, and does not take into account neither weight incidence, thoracic surgical history nor ethnic differences (8). In their literature review in 2013, Barnard *et al.* (2) established new size matching recommendations for the ISHLT: in the absence so far of reliable guidelines for assessing recipient's actual TLC, the authors suggest that it is acceptable to select a transplant

from a donor whose pTLC is within 15% to 20% of the mean of the recipient's pTLC and mTLC. Loizzi *et al.* also recommend using this ratio to choose between whole LTx and lobar transplantation (20), despite poor outcomes for lobar LTx. Although chest diameter, chest X-ray, anthropometry, weight and other factors have been used in the past to predict lung volume (4,5), LTx teams are still looking for a new and more accurate indicator of recipients' actual chest cavity volume (21). Delayed chest closure cannot be considered a safe option when graft oversizing is predictable (22).

CT scan for graft sizing

The difficulty of graft sizing urged the need for new tools to better evaluate lung volumes in transplantation. Among them, volumetric measures by CT scan is a reliable way to evaluate the volumes of each lung under forced inspiration and thus obtain an approximation of the TLC (10,12,23,24). This technique has already been applied in the particular setting of living donor LTx. Thus, Kojima *et al.* and Chen-Yoshikawa *et al.* described the use of 3D CT scan reconstructions for the elaboration of surgical strategy and sizing matching in this specific indication (13,25). However, these interesting results cannot be generalized to regular bilateral or single LTx techniques. Benefits from CT scan has already been highlighted for deceased donors, but in a very heterogeneous and non-Western recipient population (17,26). Since all transplant recipients have at least one CT scan in their pre-operative assessment and all potential donors are evaluated with a CT scan, this may allow a better fitting than plethysmography or anthropometry (27). This benefit may be particularly true for single LTx during which it may allow an accurate measurement of lung volume on the transplanted side (28). This can provide a better match than an overall analysis of both lungs and the patient's respiratory function tests (29,30). In our experience of single LTx for pulmonary fibrosis, main intra-operative difficulties are related to oversizing of the pulmonary graft on the left side. Our study confirms this clinical feeling: measured size of the rib cage in recipients with ILD is much smaller than the mTLC and pTLC values that are currently used as calibration for graft selection, especially on the left side. The significant correlation between ctTLC and mTLC is another element showing that CT volume corresponds to a functional reality and should make this variable an essential tool for graft selection: similar correlation has been highlighted by Hussain *et al.* in ILD (31). Jung *et al.*

found that ctLV showed a better correlation with mTLC compared to pTLC in patients with obstructive disease but a similar correlation with mTLC compared to pTLC in patients with restrictive pulmonary disease: the number of patients included in the restrictive group were limited (n=37) compared to the obstructive group (n=110), which might explain the absence of a significant difference in the restrictive group (17).

Study limitations

Our study has technical and methodological limitations. From the technical standpoint, determination of mTLC and ctTLC might be difficult to obtain in patients with end-staged lung disease. In this setting, the apnea required for CT scanning is short and might be easier to obtain than the quiet breath with obstructed mouth required for plethysmography. Moreover, the volumes measured by CT volumetry and plethysmography may differ because of the way CT acquisition was made. In our hospital, patients are breath-hold-coached by a standard voice recording during CT acquisition, but it has been shown in a study in severe chronic obstructive pneumopathy disease patients with emphysema that spirometry gating in CT helps to improve agreement with body plethysmography results (32). Indeed, in the study by Bakker *et al.*, the mean ± SD CT-derived TLC was 280±340 mL lower compared to body plethysmography in the gated group (n=100), and 590±430 mL lower for the non-gated group (n=100) (both P<0.001) (32). Such difference needs to be confirmed in restrictive patients.

The other technical difficulty encountered in our study was in patients transplanted in high emergency with bilateral pneumothoraces and subcutaneous emphysema, requiring manual contouring of the rib cage. From the methodological point of view, interpretation of the results must take into account time between completion of PFTs, CT scan, and transplantation; rapid deterioration of lung function in some of these patients may have caused confusion bias. However, this reflects everyday practice, where LTx candidates undergo PFTs at the time of listing and CT scan during a median waiting time of 7 months. The results from this study could benefit a prospective trial evaluating impact of size matching by D-R ctTLC ratio on postoperative outcomes. Indeed, by improving size matching with CT volume, we may better anticipate short and long-term outcomes. Prabhu *et al.* have demonstrated, by comparing pTLC ratio (calculated by dividing the

donor pTLC by the recipient pTLC) with volumetric ratio (calculated by dividing the donor pTLC by the recipient ctTLC), that undersizing was independently associated with significantly lower odds of PGD unlike the pTLC ratio (33): this was confirmerd by Vazquez Guillamet *et al.* who found that larger donor and smaller recipient lung volumes estimated by CT predicted a need for surgical graft reduction and were associated with higher PGD grade (34). Concerning long-term outcomes, using the volumetric ratio, oversizing was independently associated with a higher risk of death unlike the pTLC ratio (33).

Conclusions

CT determination of TLC and respective volumes of the right and left lung is feasible in patients with end-staged ILD awaiting transplantation. The obtained ctTLC is much lower than mTLC and pTLC, with ctTLC being significantly correlated to mTLC. Every donor in France has a Thorax CT before the organs are proposed to the transplantation team. Using thorax CT from both donors and recipient to assess size-matching instead of relying only on pTLC from donor and both pTLC and mTLC from recipients might reduce both oversizing and undersizing and therefore have an impact on outcomes. This study highlights potential size mismatch for graft selection before LTx, in ILD and opens the perspective of a prospective trial evaluating impact of size matching by D-R ctTLC ratio on postoperative outcomes.

Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1586/rc

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1586/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1586/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All patients signed an informed consent to authorize prospective data collection and retrospective data analysis. The database was declared to the French Commission for Informatics and Freedom (Commission National Informatique et Liberté, CNIL, authorization 1866407v0). The study of patients' outcome was approved by the Regional Committee for Person Protection (Comité de Protection des Personnes - Ile de France, CPP-IDF2, EudraCT/IRB 2017-A01714-49). The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

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