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RESEARCH ARTICLE

Outcomes of patients awaiting lung transplantation after the implementation of donation after brain death at a single Chinese center

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Abstract **Voluntary contribution has become the only source of donor lungs in China since 2015. To elaborate the outcomes of patients awaiting lung transplantation (LTx) after the implementation of donation after brain death, we performed a retrospective study that encompassed 205 patients with end-stage lung disease who registered for LTx at Shanghai Pulmonary Hospital from January 1, 2015 to January 1, 2021. A total of 180 patients were enrolled in the study. The median waiting time was 1.25 months. Interstitial lung disease (ILD) (103/180, 57.2%) and chronic obstructive pulmonary disease (COPD) (56/180, 31.1%) were the most common diseases in our study population. The mean pulmonary artery pressure (mPAP) of patients in the died-waiting group was higher than that of the survivors (53.29±21.71 mmHg vs. 42.11±18.58 mmHg, *P*=0.002). The mortality of patients with ILD (34/103, 33.00%) was nearly twice that of patients with COPD (10/56, 17.86%) while awaiting LTx (*P*=0.041). In the died-waiting group, patients with ILD had a shorter median waiting time than patients with COPD after being listed (0.865 months vs. 4.720 months, *P*=0.030). ILD as primary disease and mPAP > 35 mmHg were two significant independent risk factors for waitlist mortality, with hazard ratios (HR) of 3.483 (95% CI 1.311–9.111; *P*=0.011) and 3.500 (95% CI 1.435–8.536; *P*=0.006). Hence, LTx is more urgently needed in patients with ILD and pulmonary hypertension.**

Keywords lung transplantation; donation after brain death; waitlist

Introduction

Lung transplantation (LTx) is the final option for patients with end-stage lung disease [1], and approximately 4500 transplantations are performed worldwide annually [2]. The first clinical lung transplantation in China was performed nearly 40 years ago, and the number of cases performed increases during the last 2 decades. However, the lack of legal progress in organ donation and allocation markedly hinders its rapid growth. In January 2015, the Chinese government developed a new national program for deceased organ donation and halted the use of organs from executed prisoners. Since then, civilian organ donation after brain death has been the only source for organ transplantation in China [3]. We previously published a study that showed the outcome of patients waiting for LTx and the predictors for death [4]. The purpose of the present retrospective study was to further characterize the risk factors for waitlist mortality in the Chinese population and to identify the changes in outcome after the implementation of donation after brain death.

Methods

Study design

Herein, we retrospectively analyzed patients with end-stage lung disease who intended to undergo LTx at the Shanghai Pulmonary Hospital from January 1, 2015 to January 1, 2021. LTx was indicated for patients who manifested a high risk of death within 2 years due to lung

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disease [5]. Organ allocation was conducted impartially and transparently by the China Organ Transplant Response System (COTRS) [6]. All patients were classified into two groups, those who died while awaiting LTx (died-waiting group) and those who were still waiting or underwent LTx successfully (alive-waiting group). The status of all patients, including their date of death or transplantation, was confirmed at the end of the study period (February 1, 2021). Waiting time was defined as the time from the date of registration until date of death before transplantation, date of transplantation, or study deadline (February 1, 2021).

Data collection and analysis

We collected patients' variables including age, sex, height, weight, primary disease, comorbidity (diabetes and hypertension), blood type, arterial blood gas analysis, mechanical ventilation requirements, steroid hormone requirements, pulmonary function tests, and pulmonary arterial pressure. We also included follow-up information, such as date of operation, survival status, and date of death.

Statistical analysis

Statistical analysis was performed using SPSS 19.0 for Windows software system (SPSS Inc., Chicago, IL, USA). Data were expressed as mean ± SD for continuous variables that followed normal distribution. Median (P25, P75) was used to describe data that did not fit normal distribution. Data were expressed as numerical values and percentages for categorical variables. For continuous variables, we used Student's t-test or Mann–Whitney U test to analyze differences between groups. Pearson's Chi-square or Fisher's exact test was used to compare categorical variables among groups. Overall survival was analyzed by Kaplan–Meier technique, and differences in survival were assessed with log-rank test. Risk factors for waitlist mortality were determined using Cox regression analysis. Only variables with P value less than 0.1 after univariate Cox analysis were subjected to multivariate COX analysis. All tests were two sided, and a P value < 0.05 was considered statistically significant.

Results

Characteristics and outcome of patients

For this study, we registered 205 patients for LTx from January 1, 2015 to January 1, 2021 and excluded 25 patients. Pediatric (age < 18 years) patients, patients who could not afford the medical cost, and those who could not be contacted before LTx were excluded from the study. A total of 180 patients were enrolled by the end of the study period, and the vast majority of whom were men (151/180, 83.9%). The characteristics and outcomes of all patients are presented in Table 1. The median waiting time was 1.25 months (range: 0.03–37.37 months). The oldest patient was 78 years old. Two-thirds of the patients were over 60 years old. Interstitial lung disease (ILD) (103/180, 57.2%) and chronic obstructive pulmonary disease (COPD) (56/180, 31.1%) were the most common diseases in our study population. Fifty-one patients (28.3%) died while waiting for LTx (died-waiting group). In the alive-waiting group, 124 patients (68.9%) underwent LTx successfully, while 5 patients (2.8%) were still waiting for surgery until February 1, 2021. No significant differences in age, body mass index (BMI), ratio of PaO_2/FiO_2 (PF ratio), steroid hormone application, comorbidity, and median waiting time were found between the died-waiting group and the alive-waiting group. The mean pulmonary artery pressure (mPAP) of patients in the died-waiting group was higher than that of the survivors (53.29 ± 21.71 mmHg vs. 42.11 ± 18.58 mmHg).

Regarding the preoperative parameters before LTx, only 14.44% (26/180) patients needed mechanical ventilation while waiting LTx. However, these patients had higher mortality (14/26, 53.8%, P = 0.002). About 15.56% (28/180) of the patients were treated with extracorporeal membrane oxygenation (ECMO). Most of them were treated intraoperatively (78.57%, 22/28), while only six cases were treated preoperatively. Ninety patients completed pulmonary function test, but only 11 patients in the died-waiting group. Lung function and arterial blood gas data were better in the alive-waiting group than in the died-waiting group (P < 0.05, Table 1).

In terms of the waiting time of LTx, the median waiting time of patients who underwent LTx was 1.30 months, while the median waiting time of patients in the died-waiting group was 1.13 months. The mortality of patients with ILD (34/103, 33.00%) was nearly twice that of patients with COPD (10/56, 17.86%) while waiting LTx (P = 0.041, Table 1). In the died-waiting group, patients with ILD had a shorter median waiting time than patients with COPD after being listed (0.865 months vs. 4.720 months, P = 0.030).

Survival analyses

The influence of all parameters on survival while awaiting LTx was further illustrated by survival estimates using Kaplan–Meier method. The one-year overall survival rates among patients with ILD were 23.0% (95%CI 2.6%–43.4%) and 74.9% (95%CI 54.7%–95.1%) among patients with COPD (P = 0.002) (Fig. 1C). The survival estimates revealed that patients with PF ratio > 200 mmHg and mPAP ≤ 35 mmHg had better 1-year survival rate (54.1% vs. 28.4%, P = 0.028; 68.4% vs. 36.8%, P = 0.001) (Fig. 1A and 1B). No statistically

Table 1 Variables of patients with end-stage lung diseases waiting for LTx

Variables	All patients ($N = 180$)	The alive-waiting group ($N = 129$)	The died-waiting group ($N = 51$)	Value	P value
Age, year	60.37 ± 10.60	60.96 ± 10.19	58.88 ± 11.53	1.188[a]	0.237
BMI, kg/m^2	21.18 ± 3.71	20.99 ± 3.58	21.83 ± 4.08	−1.183[a]	0.239
mPAP, mmHg	44.75 ± 19.87	42.11 ± 18.58	53.29 ± 21.71	−3.111[a]	0.002
Lung function test[d]					
FEV_1, % predicted	64.52 ± 26.32	66.75 ± 26.07	48.51 ± 23.26	2.200[a]	0.030
FVC, % predicted	54.67 ± 19.86	55.43 ± 19.95	49.16 ± 19.17	0.982[a]	0.329
Arterial blood gas analysis					
PaO_2, mmHg	74.00 ± 19.75	76.11 ± 20.16	68.48 ± 17.67	2.326[a]	0.021
$PaCO_2$, mmHg	45.29 ± 13.60	45.71 ± 12.38	44.21 ± 16.45	0.653[a]	0.515
PF ratio, mmHg	244.34 ± 73.05	255.50 ± 70.61	215.18 ± 71.94	3.382[a]	0.001
Blood type, n (%)				1.027[b]	0.795
A	54 (30.00%)	38 (29.46%)	16 (31.37%)		
B	51 (28.33%)	36 (27.91%)	15 (29.41%)		
AB	17 (9.44%)	14 (10.85%)	3 (5.88%)		
O	57 (31.67%)	41 (31.78%)	16 (31.37%)		
Comorbidity					
Hypertension, n (%)	27 (15.00%)	18 (13.95%)	9 (17.65%)	0.391[b]	0.532
DM, n (%)	23 (12.78%)	18 (13.95%)	5 (9.80%)	0.565[b]	0.452
Primary diseases, n (%)				4.161[b]	0.041
ILD, n (%)	103 (57.22%)	69 (53.49%)	34 (66.67%)		
COPD, n (%)	56 (31.11%)	46 (35.66%)	10 (19.61%)		
Others[e], n (%)	21 (11.67%)	14 (10.85%)	7 (13.73%)		
Use of steroid, n (%)	32 (17.78%)	20 (15.50%)	12 (23.53%)	1.611[b]	0.204
Use of MV, n (%)	26 (14.44%)	12 (9.30%)	14 (27.45%)	9.742[b]	0.002
Waiting time, month	1.25 (0.58, 3.49)	1.40 (0.63, 3.25)	1.13 (0.37, 4.67)	3172.5[c]	0.710

All data are shown as mean ± SD analyzed by Student's t-test or median (P25, P75) analyzed by Mann–Whitney U test. All categorical variables are analyzed by Chi-square test.
[a]t values. [b]χ^2 values. [c]U value. [d]90 patients completed pulmonary function test, only 11 patients in the died-waiting group. [e]Including diseases: bronchiectasis, pneumoconiosis, idiopathic pulmonary hemosiderosis, pulmonary lymphangioleiomyomatosis (PLAM), pulmonary veno-occlusive disease (PVOD), inhalation pulmonary injury, bronchiolitis obliterans (BO), pulmonary hypertension (PH), and lung injury due to paraquat poisoning.
Abbreviations: BMI, body mass index; mPAP, mean pulmonary arterial pressure; FEV_1, forced expiratory volume at one second; FVC, forced vital capacity; DM, diabetes mellitus; COPD, chronic obstructive pulmonary disease; ILD, interstitial lung disease; MV, mechanical ventilation; PF ratio, ratio of PaO_2/FiO_2.

significant difference in survival was found between patients requiring mechanical ventilation (MV) or not (P = 0.414) (Fig. 1D). The Cox regression analysis further showed that ILD as primary disease and mPAP > 35 mmHg were two significant independent risk factors for waitlist mortality, with hazard ratios (HR) of 3.483 (95% CI 1.311–9.111; P = 0.011) and 3.500 (95% CI 1.435–8.536; P = 0.006), respectively (Table 2).

Discussion

Lung transplantation is the most well-established treatment option for selected patients with end-stage pulmonary disease. An increasing number of LTx cases has been performed worldwide, and over 4500 patients underwent LTx in 2016 [2]. Although China has ranked second in the demand for organ transplants worldwide [7], only 1/3 of patients have undergone this critical surgery due to the shortage of donors [7]. The traditional Chinese beliefs on life and death affect the willingness of people to donate their organs; as such, organs harvested from executed prisoners have become the principal donor source during the past three decades [8,9]. To solve this problem, the Chinese government has made great strides in the organ-donation process; since January 2015, the primary source for organ transplantation in China has been civilian organ donation after brain death [3].

The number of donors may increase more rapidly in the future after perceptions regarding organ donation change, and this may shorten the waiting period [10]. All information regarding donors is currently available through COTRS [11]. In the present study, the mortality was 28.3%, similar to our previous investigation [4]. The median waiting time was 1.25 months, which could be

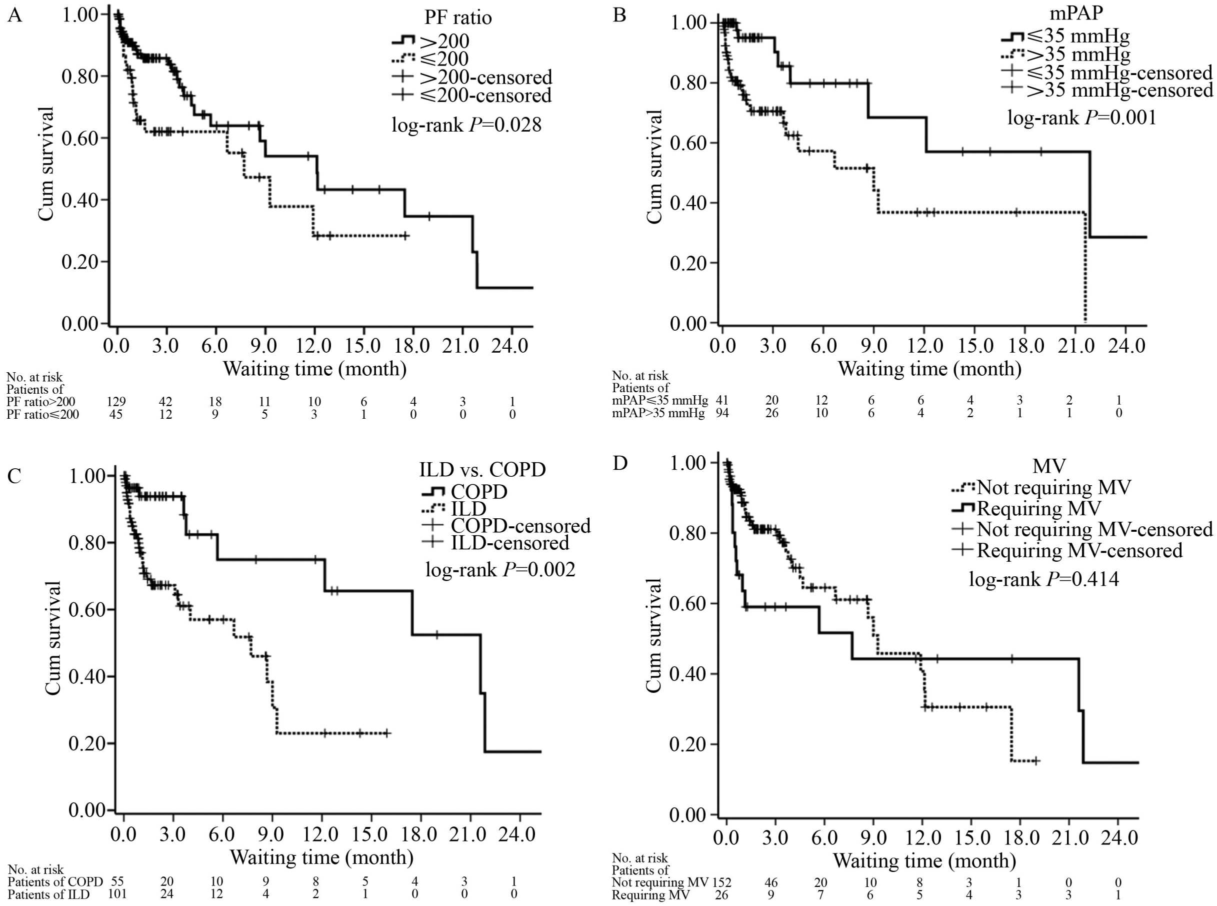

Fig. 1 Cum survival: survival of patients awaiting lung transplantation, determined by the Kaplan−Meier method. (A) Differences in survival between patients with PF ratio > 200 mmHg versus those with PF ratio ≤ 200 mmHg were statistically significant (P = 0.028). (B) Differences in survival between patients with mPAP ≤ 35 mmHg versus those with > 35 mmHg were statistically significant (P = 0.001). (C) Differences in survival between patients with ILD versus those with COPD were statistically significant (P = 0.002). (D) No statistically significant difference in survival was found between patients requiring MV versus those not requiring MV (P = 0.414). mPAP, mean pulmonary arterial pressure; COPD, chronic obstructive pulmonary disease; ILD, interstitial lung disease; MV, mechanical ventilation; PF ratio, ratio of PaO_2/FiO_2.

Table 2 COX proportional hazards analysis for all patients

Variables[a]	Univariate analysis		Multivariate analysis	
	P value	HR (95% CI)	*P* value	HR (95% CI)
PF ratio, > 200 mmHg	0.032	0.527 (0.294−0.945)	0.563	
ILD vs. COPD	0.001	3.922 (1.718−8.950)	0.011	3.483 (1.311−9.111)
mPAP, > 35 mmHg	0.002	3.612 (1.580−8.258)	0.006	3.500 (1.435−8.536)

[a]Only three variables with a *P* value less than 0.1 were available for multivariate COX analysis. All the other variables were excluded after univariate COX analysis. Abbreviations: ILD, interstitial lung disease; COPD, chronic obstructive pulmonary disease; PF ratio, ratio of PaO_2/FiO_2; HR, hazard ratio; 95% CI, 95% confidence interval.

related to ongoing developments in organ donation in China. China has exhibited the second largest absolute number of organ donation and transplantation worldwide since 2015. In fact, in 2018, the number of organ donations after citizen death exceeded 6000 cases in China [12]. Compared with kidney or liver transplantation, only a miniscule percentage of the donated lungs were used for LTx. In 2017, only 299 lung transplantations were performed in China, indicating that only about 5% of donor lungs were utilized effectively [11]. This incidence might be related to several factors. First, many patients with end-stage lung disease were concerned about the surgery, and their medical conditions were usually too severe to allow waiting for the lung donors. Second, some respiratory physicians may not have known that early LTx evaluation for these patients is the key to decreasing the waiting mortality. Most importantly, many ICU physicians could not properly maintain the donor lungs, leading to the wastage of potential organs. Results from trials and studies [13] that evaluated *ex vivo* lung perfusion (EVLP) showed similar survival rates between the EVLP group and the control group. EVLP is considered to be a technique with a high potential for clinical application in lung transplantation to expand the donor pool.

Pulmonary hypertension occurs in numerous patients with end-stage lung disease. A study on 56 patients conducted by Arcasoy *et al.* [14] showed that the development of pulmonary hypertension resulted in right ventricular dysfunction, which was closely related to mortality. Paik *et al.* [15] believed that the mortality rate of patients with primary pulmonary hypertension on the waiting list for LTx was also higher (62.5%). In the present study, we showed that the mPAP of patients in the died-waiting group was higher than that in the alive-waiting group, similar to our previous investigation [4]. Compared with patients with mPAP ≤ 35 mmHg, those with mPAP > 35 mmHg had worse 1-year survival rate (85.37% vs. 69.15%, P = 0.001) and increased risk of death by 3.5 times (Fig. 1B and Table 2). Thus, patients with pulmonary hypertension should be given priority on waiting list.

ILD, significantly exceeding COPD (57.22% vs. 31.11%), had been the most common indication for LTx in our study. This finding was contrary to our previous research [4] but consistent with the conclusion of the 30-sixth Adult Lung and Heart-Lung Transplantation Report in 2018 [2]. The pulmonary function of patients with ILD usually deteriorates too quickly to await a reasonable donor, as fewer than 1/3 of patients with ILD survive more than 5 years [5]. A systematic review [16] showed that waitlist mortality ranged from 14% to 67% and was higher for patients with ILD than for other patients. In the present study, the mortality of patients with ILD (33.00%) was higher than that of patients with COPD (17.86%) awaiting LTx (P = 0.041). In the died-waiting group, patients with ILD exhibited shorter waiting time for LTx than patients with COPD (0.865 months vs. 4.720 months, P = 0.030). The median waiting time of patients who underwent LTx successfully was 1.30 months, which was longer than that of patients with ILD in the died-waiting group (0.865 months). This finding indicates that many patients with ILD do not have enough time to wait for suitable lung donor on the waitlist. On the other hand, we found that ILD as diagnosis was independently associated with waitlist mortality by multivariate COX analysis, similar to the results of our previous study [6]. Pulmonary hypertension (PH) is also an important complication of ILD. Wang *et al.* [17] found that patients with ILD and PH had more severely impaired exercise capacity and cardiac function than patients with ILD without PH. Therefore, we recommend that pulmonary circulatory hemodynamics and right-heart function should be evaluated on every patients with ILD prior to LTx, and that patients with ILD, particularly those with pulmonary hypertension, should be given priority while awaiting LTx.

The Lung Allocation Score (LAS) is a scoring system used to distribute donated lungs equally and appropriately. The LAS system was introduced in the US in May 2005 and was adopted in Germany in December 2011 and in the Netherlands in April 2014 [18]. The LAS considers the 1-year survival after LTx and medical urgency and aims to direct organs to recipients who are predicted to experience the greatest potential for transplantation survival. In the United States and Germany, the transplantations increased and the waitlist mortality decreased after the introduction of the LAS [19,20]. The LAS was introduced in China in 2018, and the COTRS now ranks recipients according to the LAS, which determines the waiting order. Tang *et al.* [21] showed that urgently listed patients were sicker overall and needed to be treated as a separate sub-category. Appropriate patient selection and aggressive supportive care thus allow urgently listed lung-transplant patients to demonstrate outcomes similar to those of electively listed patients. However, an urgency list is currently not available in China. We therefore hope that our research will help in establishing an urgency list for LTx in China.

This study has several limitations. It adopted a single-center, continuous, retrospective design, which may have engendered information and selection biases. However, this study is the first to focus on waitlist death and survival since the introduction of donation after brain death in China. Patients with better outcome from LTx should be prioritized in the list. However, analysis of the outcome of post-transplantation is difficult in our study.

In conclusion, we described the outcome of patients waiting for LTx after the implementation of donation after brain death in China. ILD as diagnosis and mPAP > 35 mmHg were independent risk factors of mortality on the waiting list. We believe that LTx is more urgently needed in patients with ILD and pulmonary hypertension.

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Compliance with ethics guidelines

Yuling Yang, Xinnan Xu, Ming Liu, Yanfeng Zhao, Yongmei Yu, Xiaogang Liu, Chang Chen, Gening Jiang, and Wenxin He declared no conflicts of interest. This study was approved by the Ethics Committee of the Shanghai Pulmonary Hospital of Tongji University.

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