Lung transplantation in China between 2015 and 2018

Chun-Xiao Hu[1,2,3], Wen-Hui Chen[4], Jian-Xing He[5], Ge-Ning Jiang[6], Xiao-Shan Li[1,2,3], Dong Wei[1,2,3], Bo Wu[1], Ji Zhang[1], Chen Wang[4], Jing-Yu Chen[1,2,3,4]

[1]Wuxi Lung Transplant Center, Wuxi People's Hospital affiliated to Nanjing Medical University, Wuxi, Jiangsu 214043, China;
[2]Chinese Lung Transplantation Quality Management and Control Center, Wuxi, Jiangsu 214043, China;
[3]Chinese Lung Transplantation Registry and Data Management Center, Wuxi, Jiangsu 214043, China;
[4]Center for Lung Transplantation, China-Japan Friendship Hospital, Beijing 100029, China;
[5]Department of Thoracic Surgery/Oncology State Key Laboratory and National Clinical Research Center for Respiratory Disease, The First Affiliated Hospital of Guangzhou Medical University, Guangzhou, Guangdong 510120, China;
[6]Department of Thoracic Surgery, Shanghai Pulmonary Hospital, Tongji University School of Medicine, Shanghai 200433, China.

Abstract

Background: Lung transplantation (LT) has been demonstrated as the only effective therapy for patients with end-stage lung diseases. Increasing listed lung transplant candidates and expanding volumes of lung transplant centers across China require well-organized programs and registry data collection based on the large population. This study aimed to summarize and analyze the data of LT development in China.

Methods: We retrospectively collected and analyzed data from the China Lung Transplantation Registry (CLuTR). Key data were reported from the registry with transplant types, indications, donor and recipient characteristics, outcomes and survival. The survival <30 days, 1-year and 3-year survival rates were estimated with risk factors identified.

Results: CLuTR contained data from 1053 lung transplants performed through January 1st, 2015 to December 31st, 2018 reported by 18 registered transplant centers. The largest category of diagnosis before transplantation was idiopathic interstitial pneumonitis. The total <30 days, 1-year and 3-year survival rates in CLuTR were 81.45%, 70.11%, and 61.16% with discrepancy by indications. Large proportion of recipients who were more than 60 years old required higher standard of care. Infection-related complications resulted in more death events in the early post-surgery periods. New York Heart Association grading at listing, extra-corporeal membrane oxygenation usage peri-transplantation, allograft dysfunction (primary graft dysfunction >Grade 0), renal insufficiency (estimated glomerular filtration rate <60 $mL \cdot min^{-1} \cdot 1.73\ m^{-2}$), were independently associated with a higher risk for 3-year mortality in the entire cohort.

Conclusions: Facing more end-stage of lung diseases and comorbidities, this study analyzed the outcomes and survival of LT recipients in China. Further prospectively stratified analyses with longer follow-up will be needed.

Keywords: Lung transplantation; China; Organ donation; Survival; Quality

Introduction

Approximately 4600 lung transplantations (LTs) have been performed annually around the world.[1] The number of patients on the waiting list in China has been increasing continually. LT has developed rapidly with advancement of organ preservation and surgical techniques, immunosuppressive regimens, and criteria refinement.[2,3] However, due to the complexity of the perioperative management of the recipients, it is still challenging to establish and maintain a sustainable lung transplant program to diminish the geographic disparity and balance the supply and demand.[4]

The number of LTs in China has been growing year by year since the fully establishment of China Lung Transplantation Registry (CLuTR). With the support from the government, the Chinese Lung Transplantation Registry and Data Management Center has been functioned since 2010. Up to February 2019, there have been thirty-eight qualified LT centers nationwide. We have summarized and analyzed the data of LT development in China from CLuTR.

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Correspondence to: Dr. Jing-Yu Chen, Wuxi Lung Transplant Center, Wuxi People's Hospital Affiliated to Nanjing Medical University, Wuxi, Jiangsu 214043, China
E-Mail: chenjy@wuxiph.com

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Methods

Study population

We retrospectively analyzed the nationwide data of CLuTR from the 4-year period from January 1st, 2015 to December 31st, 2018. The International Thoracic Organ Transplant (TTX) Registry database report[1] was used to benchmark Chinese recipients' outcomes.

Ethical approval

As the study was retrospective and data analysis was performed anonymously, this study was exempt from the ethical approval and informed consent from patients.

Variables

In general, the registry collected pre-transplant baseline data, and post-transplant data at hospital discharge and annual follow-up. Baseline data included date of transplant, age at transplant, gender, body mass index (BMI), blood type, and primary diagnostic indication for lung transplant. Donor characteristics included age, BMI, blood type, donation type, size match, fraction of inspired oxygen, and ventilation time, were collected through the China Organ Transplant Response System (www.cot.org.cn).

Peri-operative and post-operative factors, such as mechanical ventilator use or extra-corporeal membrane oxygenation (ECMO) use before and after transplantation, intensive care unit (ICU) duration and hospitalization duration, were analyzed. Events of graft dysfunction, acute rejection, and infection were also reviewed. The registry received survival data from its participating sites and collectives. Patient status (including living, dead, lost-to-follow-up) was recorded with date and cause of death. The final set of estimates and *P* values were conducted by pooled data collected.

Statistical analysis

A retrospective explorative analysis was performed. The demographic data relating to donors, recipients, and transplants were displayed as numbers and percentages. Continuous data presented as median (interquartile range [25th–75th percentile]). The comparison of continuous and categorical variables was performed using the Student's *t* test or the Mann-Whitney *U* test, Chi-square or Fisher exact test, respectively. Survival rates after LT were plotted by the Kaplan-Meier method and compared with the Log-Rank test [also see in Supplementary File 1, http://links.lww.com/CM9/A119]. Multivariate Cox proportional hazards regression was used for time-to-event analyses and compared the adjusted hazard ratio for mortality. The analysis cohort for the Cox model was run on 575 patients having complete data for all variables in the model. All calculations and comparisons were performed using SPSS version 20 (SPSS Inc., Chicago, IL, USA) and GraphPad Prism 7 (GraphPad Software Inc., La Jolla, CA, USA). A *P* value less than 0.05 was considered statistically significant.

Results

Lung transplant centers and transplant activity

CLuTR contained data from 1053 lung transplants [Figure 1A] performed in 4-year period reported by 18 registered transplant centers [Figure 1B]. The number of reported lung transplants each year was stratified by procedure types (bilateral lung transplants [BLT] or single lung transplants [SLT]). Higher-volume (>30 transplants per year) centers performed approximately 80% of the procedures despite comprising 3/18 of the case-reported centers and 3/38 of the total qualified lung transplant centers [Figure 1B]. In the mainland of China, Wuxi center (WX) transplanted 100+ cases in average of the consecutive years. Followings were China-Japan Friendship Hospital (CJ), First Affiliate Hospital of Guangzhou Medical University (GZ), and Shanghai Pulmonary Hospital (SHP) [Supplementary Figure 1, http://links.lww.com/CM9/A120].

Median age of recipients were 55.0 years (5.0–82.0) and proportion of male recipients was 83.2%. The percentage of recipients within normal range of BMI (18.5–24.0 kg/m^2) was 58.6%. The percentage of blood types O, A, B, AB, were 31.4%, 28.3%, 29.8%, and 10.5%, respectively [Table 1, Supplementary Table 1, http://links.lww.com/CM9/A124].

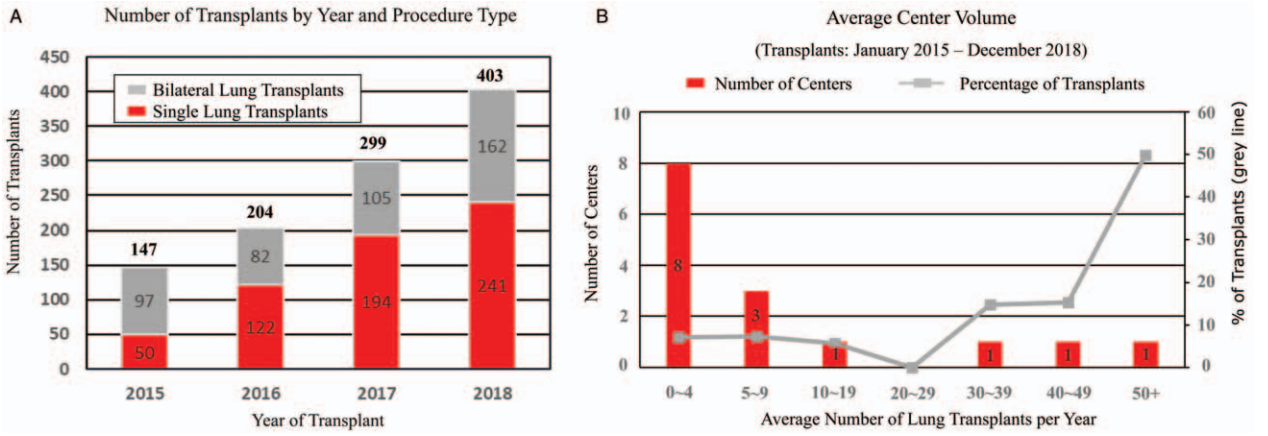

Figure 1: Lung transplant activity in China from January 2015 to December 2018. (A) Number of transplants by year and procedure types; (B) average number of lung transplants per year.

Table 1: Recipient characteristics in CLuTR (January 2015–December 2018).

Characteristics	Values	Characteristics	Values
Baseline			
Age (years)		Diagnosis (%)	
Recipient	55.0 (5.0–82.0)	IIP	39.0
Donor	36.0 (11.0–62.0)	COPD	23.0
		ILD-not IIP	13.2
		Pneumonoconiosis	9.2
		Non-CF bronchiectasis	4.8
		Pulmonary hypertension	3.5
		LAM/tuberous sclerosis	1.9
		Re-transplantation	2.1
		Obliterans bronchiolitis	1.1
		Broncho-dysplasia	0.3
		Scleroderma	0.3
		Eisenmenger syndrome	0.3
		Others	1.3
BMI (%)		Comorbidities (%)	
<18.5 kg/m^2	25.7	Diabetes	14.5
18.5–24.0 kg/m^2	58.6	Hypertension	12.7
>24.0 kg/m^2	15.7	Coronary artery diseases	3.5
		Malignancy	1.3
		Peptic ulcer	1.3
		Pulmonary embolism	1.0
		Peripheral vasculopathy	0.7
		Cerebral vascular diseases	0.6
Blood type (%)		Other medical history (%)	
O	31.4	Steroids	39.5
A	28.3	Vasoactive drugs	10.1
B	29.8	Transfusion	6.7
AB	10.5	Thoracic surgery	3.1
		History of dialysis	1.1
		Chemotherapy for cancer	0.5
Surgical and post-transplantation outcome			
Ischemic time (min)		In-hospital stay (%)	
SLT	360.0 (247.5–430.0)	0–7 days	8.6
		8–10 days	4.3
BLT	480.0 (360.0–570.0)	10–14 days	4.1
		15–21 days	8.1
		22–28 days	10.9
		≥29 days	64.0
Operation time (min)		Post-transplant events, <30 days (%)	
SLT	260.0 (206.0–320.0)	Acute infection	68.3
		Primary graft dysfunction	15.6
BLT	390.0 (335.0–465.0)	Acute rejection	17.4
		Renal dysfunction	16.0
		Diabetes	9.2
		Broncho-pleural fistula	6.4
		Anastomotic lesions	5.9
		Cardiovascular	1.0
		Hypertension	2.7
		Hyperlipidemia	2.5
		Hypercholesteremia	1.7
		PA/V anastomotic lesions	0.5
		Obliterans bronchiolitis	0.3
		Malignancy	0.2
Complications, intra-operative (%)		Cause of death, <30 days (%)	
Cardiac arrest	1.5	Infection-related reparatory failure	54.8
Pulmonary Hematoma/laceration	0.4	Primary graft dysfunction	5.9
Pulmonary vascular stenosis/thrombosis	0.1	Multi-organ dysfunction	12.2
Anastomotic leak	0.3	Cardiovascular	6.8
		Hemorrhagic shock	5.4
		Other-related reparatory failure	8.1
		Anastomotic fistula	3.2
		Rejection	0.9
		Pulmonary embolism	0.5
		Post cardiac-pulmonary resuscitation	0.5
		Malignancy	0.5
		Other (including technical related)	1.2

CLuTR: China Lung Transplantation Registry; BMI: Body mass index; SLT: Single lung transplant; BLT: Bilateral lung transplants; IIP: Idiopathic interstitial pneumonitis; CF: Cystic fibrosis; COPD: Chronic obstructive pulmonary disease; ILD: Interstitial lung disease; LAM: Lymphangioadenomyomatosis; PA/V: Pulmonary arteriovenous.

Indications and pre-transplantation status

The underlying diseases of recipients from CLuTR were different from those reported in TTX registry. There was relatively low prevalence of alpha-1-anti-trypsin deficiency, cystic fibrosis, and sarcoidosis [Supplementary Table 1, http://links.lww.com/CM9/A124]. The largest category of diagnosis before transplantation was idiopathic interstitial pneumonitis (IIP) at 39.0%, followed by chronic obstructive pulmonary disease (COPD) at 23.0%. Pneumonoconiosis patients consisted of 9.2% of the cohort and lymphangioadenomyomatosis (LAM) patients had a percentage of 1.9%, which have been significantly different from the western cohort population [Figure 2A]. From the perspective of transplant types within indication [Figure 2B], SLTs were performed in pneumoconiosis, interstitial lung disease (ILD, including IIP and ILD-not IIP) with an increasing trend. However, more BLTs have been performed in pulmonary hypertension, LAM, and bronchiectasis patients demonstrated from CLuTR.

Currently, even candidates over age of 65 years routinely received assessment for LT. In the cohort, there were 46.6% of the recipients over 60 years old. Percentage of ECMO bridging was 4.9% and mechanical ventilation rate was 5.5%. New York Heart Association (NYHA) grades distribution were I/II 1.5%, III 45.6%, and IV 52.9%. Main comorbidities included diabetes at 14.5% and hypertension at 12.7%. Patients had histories of steroids or vasoactive drugs treatment, at percentage of 39.5% and 10.1% [Table 1].

Transplantation

Donated lungs were allocated nationwide; thus, guaranteed transportation route with seamless connection of civil aviation, high-speed trains, and high-ways were crucial for graft quality. Median donor age was 36.0 years (11.0–62.0) [Supplementary Figure 2, http://links.lww.com/CM9/A121], donation after brain death (DBD) donors have increased to 66.7% in 2018 [Supplementary Figure 3, http://links.lww.com/CM9/A122].

Median allograft cold ischemic time (CIT) for SLT was 360.0 (247.5–430.0) and BLT 480.0 (360.0–570.0) min [Table 1]. When further analyzed by years, from 2015 to 2018, CITs for BLT were 500.0 (365.0–602.0), 532.0 (423.8–570.0), 480.0 (360.0–567.5), and 445.0 (340.0–545.0) min, respectively, demonstrating a clear decreasing trend ($\chi^2 = 8.829$, $P = 0.032$).

Median total procedure time was 260.0 (206.0–320.0) min for SLT and 390.0 (335.0–465.0) min for BLT ($Z = 17.024$, $P < 0.001$). Bleeding volume that needed transfusion for SLT was 700 (400–1000) mL and for BLT 1100 (800–2000) mL ($Z = 9.332$, $P < 0.001$). ECMO support was used in 56.4% of the recipients during transplantation. Fatal intraoperative complications included cardiac arrest (1.5%), pulmonary hematoma/laceration (0.4%), stenosis or thrombosis formation of pulmonary veins (0.1%), and anastomotic leak (0.3%) [Table 1].

Median ICU stay for CLuTR cohort was 5.0 days (2.0–42.0). It has been shown that 47.0% of the patients stayed less than five days in ICU. Median in-hospital stay was 36.0 days (21.0–55.0), including 64.0% of the patients stayed in hospital more than 29.0 days [Table 1, Supplementary Table 1, http://links.lww.com/CM9/A124]. Re-transplantation ratio was 2.1% in total cohort.

Post-transplantation treatment and survival

For the follow-up regarding post-transplant morbidities, it has been focused on infection (68.3%), acute rejection (17.4%), renal dysfunction (16.0%), primary graft dysfunction (PGD) (15.6%), diabetes mellitus (9.2%), broncho-pleural fistula (6.4%), and bronchial anastomotic lesions (5.9%) [Table 1]. Compared to TTX report,[1] CLuTR patients had a higher incidence of infection in postoperative periods [Supplementary Table 1, http://links.lww.com/CM9/A124]. For patients who received prednisone and survived to be discharged, maintenance steroids, tacrolimus, and mofetil have been still the most common regimen at one year after transplant.

The total <30 days, 3 months, 6 months, 1-year, 2-year, and 3-year Kaplan-Meier survival rates in CLuTR were 81.45%, 74.97%, 72.24%, 70.11%, 64.85%, and

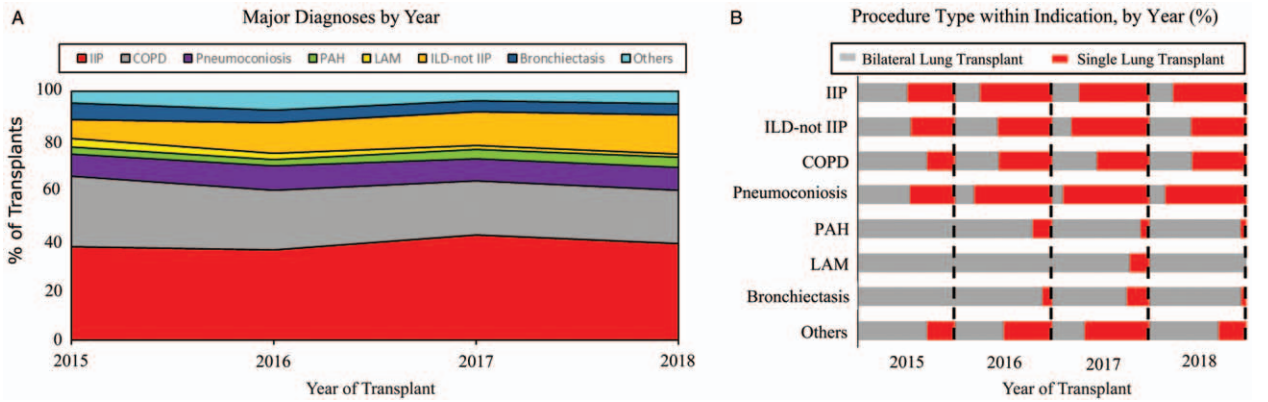

Figure 2: Indications of the transplants with type selection by year. (A) Major diagnoses by year, IIP, ILD-not IIP, COPD, pneumoconiosis, bronchiectasis, LAM were the representative indications in the registry; (B) procedure types by main indications per year ratio. COPD, Chronic obstructive pulmonary disease; IIP: Idiopathic interstitial pneumonitis; PAH, Pulmonary arterial hypertension; LAM, Lymphangioadenomyomatosis; ILD, Interstitial lung disease.

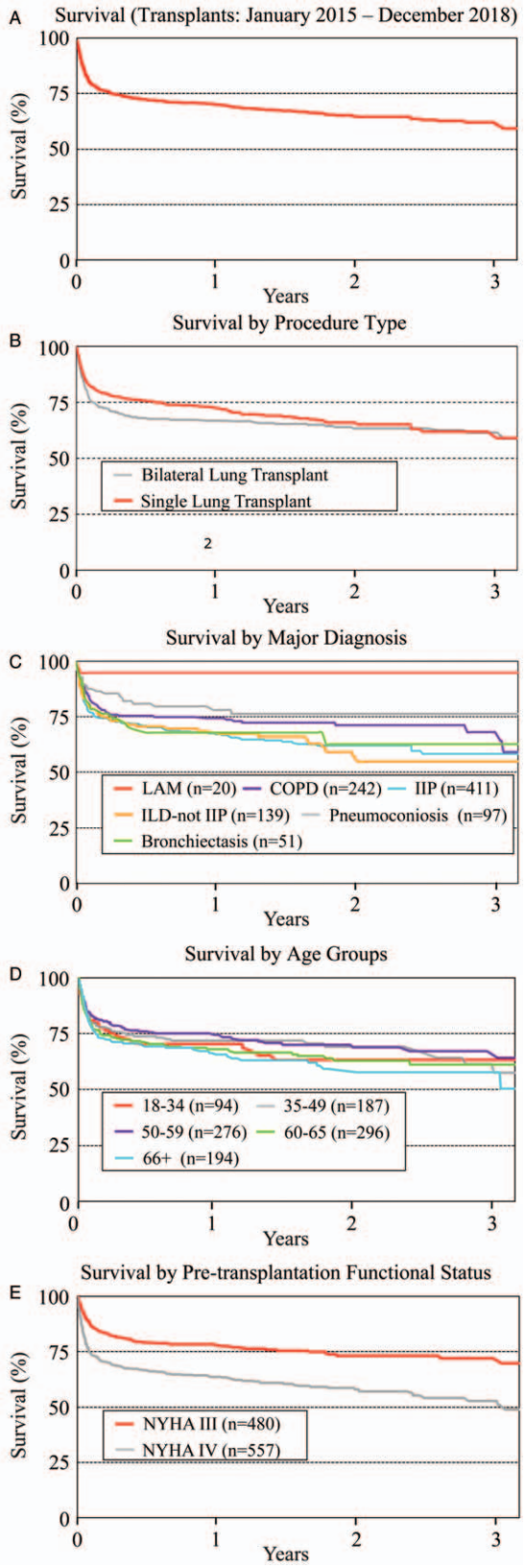

Figure 3: Kaplan-Meier survival for lung transplant recipients by transplant era (2015–2018): (A) total, (B) by transplant types, (C) by indications, (D) by age groups, (E) by functional status. Survival was calculated using the Kaplan-Meier methods with follow-ups of recipients. The survival rates were estimated rather than exact rates and compared by Log-Rank test. COPD: Chronic obstructive pulmonary disease; IIP, Idiopathic interstitial pneumonitis; ILD, Interstitial lung disease; LAM: Lymphangioadenomyomatosis; NYHA, New York Heart Association.

61.16% [Figure 3A and Table 2]. For BLT, the <30 days, 3 months, 6 months, 1-year, and 3-year Kaplan-Meier survival rates in CLuTR were 78.82%, 71.12%, 67.81%, 66.90%, and 61.57%; for SLT, the rates were 83.36%, 77.75%, 75.45%, 72.42%, and 58.99%, respectively (log-rank $P = 0.067$) [Figure 3B]. In terms of patient survival after lung transplant by disease category, patients who had LAM and pneumoconiosis as the indication for LT seemed to have superior survival compared to other main diagnosis (overall log-rank $P = 0.013$) [Figure 3C]. However, the recipients' volume was relatively small for LAM. One-year survival rate estimations demonstrated that, pneumoconiosis at 78.07%, IIP at 67.13%, LAM at 95.00%, COPD at 74.40%, bronchiectasis at 67.79%, and ILD-not IIP at 68.47% [Table 2].

When comparing the age groups, we found higher percentage of patients over 60 years old in China [Supplementary Figure 4, http://links.lww.com/CM9/A123]. Age of 66^{+} patients had a shorter survival period and lower estimated rate in the follow-up but without statistical significance (overall log-rank $P = 0.385$) [Figure 3D and Table 2], possibly contributing to the inferior survival manifestation in our registry.

We further compared the outcomes stratified by functional status (represented by NYHA grades). For 1-year and 3-year survival, NYHA III group of patients had survival rates of 77.79% and 72.04%; NYHA IV group of patients had survival rates of 63.70% and 50.95%, which were both significantly lower than that of NYHA III group (log-rank $P < 0.001$) [Figure 3E and Table 2]. Causes of 221 deaths during the post-operative admission (<30 days) included pulmonary infection related respiratory failure as the leading cause at rate of 54.8%, followed by multi-organ dysfunction (12.2%), and non-infection respiratory failure (8.1%) [Table 1].

We performed multivariable Cox proportional hazards regression analyses to identify independent factors associated with post-transplant mortality and morbidity [Table 3]. NYHA grading at listing, ECMO usage peri-transplantation, allograft dysfunction (PGD >Grade 0), renal insufficiency (estimated glomerular filtration rate <60 mL·min^{-1}·1.73 m^{-2}), were independently associated with a higher risk for 3-year mortality in the entire cohort.

Discussion

By the end of 2018, there were in total 6302 donated organs while only 5.5% of donated lungs have been transplanted, significantly lower than the global reported level. LT programs in general followed the recommendations of donor selection and management protocol.[5,6] Patients on long-term use of mechanical ventilation or machinery circulatory support, with difficulties of clearing sputum or secretions with infections, or with multi-comorbidities, can be challenging for transplantation.[7,8] However, our reported mid- to long-term survival were comparable to reported data from other countries, such as in IPF.[9] From this dataset, we could see pulmonary infection was the biggest challenge in peri-operative period

Table 2: Overall and stratified Kaplan-Meier survival for lung transplant recipients (%).

Items	<30 days	3 months	6 months	1 year	2 years	3 years
Total survival	81.45	74.97	72.24	70.11	64.85	61.16
By indications						
LAM (n = 20)	95.00	95.00	95.00	95.00	95.00	95.00
Pneumoconiosis (n = 97)	88.66	85.49	80.93	78.07	76.30	76.30
COPD (n = 242)	85.77	75.99	75.54	74.40	71.26	68.17
Bronchiectasis (n = 51)	82.35	76.42	67.79	67.79	62.58	62.58
IIP (n = 411)	79.67	73.39	70.53	67.13	61.93	58.17
ILD-not IIP (n = 139)	81.29	73.17	70.66	68.47	57.04	54.85
By age groups						
18–34 (n = 94)	81.91	75.26	70.30	70.30	63.24	63.24
35–49 (n = 187)	80.71	76.24	73.88	71.78	69.09	57.44
50–59 (n = 276)	84.58	78.86	75.97	74.48	68.85	67.25
60–65 (n = 296)	80.68	73.11	70.37	68.07	62.89	61.23
66+ (n = 194)	79.17	71.20	69.34	65.59	59.29	57.69
By functional status						
NYHA III (n = 480)	88.68	82.05	79.05	77.79	73.20	72.04
NYHA IV (n = 557)	75.53	69.07	66.29	63.70	57.88	50.95

LAM: Lymphangioadenomyomatosis; COPD; Chronic obstructive pulmonary disease; IIP: Idiopathic interstitial pneumonitis; ILD: Interstitial lung disease; NYHA: New York Heart Association.

Table 3: Characteristics associated with survival by Cox proportional hazards models in patients having data available.

Variables	*N*	β	S_x	Wald χ^2	*P*	HR (95% CI)
Functional status						
NYHA I/II/III	270					1.00
NYHA IV	305	0.602	0.167	12.921	<0.001	1.83 (1.32–2.53)
Usage of ECMO						
No	263					1.00
Yes	312	0.412	0.191	4.659	0.031	1.51 (1.04–2.19)
Allograft dysfunction						
No	488					1.00
Yes	87	1.024	0.172	35.445	<0.001	2.78 (1.99–3.90)
Renal insufficiency						
No	483					1.00
Yes	92	1.141	0.183	38.647	<0.001	3.13 (2.18–4.48)

HR: Hazard ratio; CI: Confidence interval; NYHA: New York Heart Association; ECMO: Extra-corporeal membrane oxygenation.

as well as in long-term survival. Pre-transplant status evaluation, such as NYHA grading was important to predict the long-term prognosis. Further, if patients were in critical status with multi-organ dysfunction, such as in need of ECMO support, with allograft dysfunction or renal insufficiency, they were shown to have diminished survival rate independently to age, gender, BMI, and blood types.

As China covers a vast territory, patients have access to lung transplant service including cost reimbursement covered by local governmental medical insurance, such as in Jiangsu province. A more uniformly collaborated organization called "China Lung Transplantation Alliance" has been established to promote the LT technique spreading and medical practice management as well as to share the experiences among transplant and procure surgeons, physicians, critical care intensivists, and coordinated staffs. With ever-increasing of lung transplant recipients in China, CLuTR is kept on improving and contributing to global experience.

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Conflicts of interest

None.

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