福岡大医紀（*Med. Bull. Fukuoka Univ.*）：49(2)，77–84，2022

Registry Report of Initial 50 Cases at Fukuoka University Lung Transplant Program

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Abstract

Background: Lung transplantation has been established as an effective treatment option for patients with end-stage severe lung disease. The Fukuoka University Hospital Lung Transplantation Program began registration of lung transplants in 2005. Herein, we summarize our single-center experience with performing 50 lung transplantations over the past 16 years.

Patients and methods: Between December 2005 and June 2021, 129 patients registered in the Japan Organ Transplantation Network from Fukuoka University Hospital, and 50 recipients underwent lung transplantation（five living-donor lobar lung transplantations and 45 cadaveric lung transplantations）. We retrospectively examined the patients' characteristics and outcomes. Additional analysis was performed after dividing the cohort into two groups based on cohorts（2005–2015, cohort 1, n = 52 and 2016–2021, cohort 2, n = 77）.

Results: The demographics and preoperative characteristics of cadaveric lung transplantation candidates did not significantly change over time. However, the number of registrations and the cadaveric lung transplantations performed increased in cohort 2 compared with cohort 1. Bilateral lung transplantation was performed more frequently in cohort 2. We also observed a shorter length of postoperative intensive care unit stay in the present cohort（9.5 days in cohort 2 vs. 15.7 days in cohort 1; $P = .04$）. Although there was no significant difference in the length of hospital stay between the two cohorts, acceptable 30-day and 1-year survival outcomes were achieved. The survival rate after lung transplantation at the end of 2015 and 2021 was 69.7% and 85.9% at 1 year, and 50.8% and 73.7% at 3years, respectively.

Conclusions: Although the demographic characteristics of patients over the study period did not change, the number of candidates and recipients increased significantly. A significant improvement in the 1-year and

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3-year survival was observed in the more recent cohort. Despite the limited number of cases, our program had comparable characteristics and outcomes to the international registry data.

Key words: cadaveric lung transplantation, living-donor lobar lung transplantation, lung transplantation candidate, waitlist mortality

Introduction

Lung transplantation remains a viable therapeutic option for patients suffering from end-stage lung disease. The first successful lung transplantation was reported in 1983.[1] Since then, the number of lung transplantations has steadily been increasing; 4122 lung transplantations were performed globally in 2015.[2] The Japanese lung transplantation program started in accordance with the Japanese Organ Transplant Law, which took effect in 1997. While there were only 6–10 cases of organ donations annually in the first few years, these numbers have been increasing since 2010 when the revision of the Japanese Organ Transplant Law took effect. The Registry of the Japanese Society of Lung and Heart-Lung Transplantation reported that 838 lung transplantations were performed nationwide from 1997 to 2020 in Japan.

The lung transplant program of Fukuoka University Hospital started in May 2005, and the first cadaveric lung transplantation (CLT) was performed on October 28, 2006—left lung transplantation for a patient with bronchiolitis obliterans after hematopoietic stem cell transplantation. A month later, the first living-donor lobar lung transplantation (LDLLT) was performed for a 4-year-old boy with the same pathology.[3] This was the youngest worldwide case of single lobar lung transplantation from a living related donor at that time point. Since then, a total of 50 cases of lung transplantations have been performed between October 2006 and June 2021. In the last 5 years, our program has witnessed rapid growth. The number of candidates registered in the Japan Organ Transplantation Network (JOTN) and patients receiving lung transplantation has tripled. The purpose of this report was to review the first 16 years of our program, including transplant indications, patient demographics, the types of transplantation surgery performed, and patient survival data.

Subjects and Methods

One-hundred and twenty-nine patients were referred to the Fukuoka University Hospital and registered in the JOTN for CLT in the period between 2005–2021. The selection of the candidates for lung transplantation was based on the International Society for Heart and Lung Transplantation (ISHLT) guidelines.[4] Clinical data were obtained from the lung transplantation registration database and medical records at the Fukuoka University Hospital. The study protocol was approved by the Fukuoka University Hospital's Institutional Review Board (protocol #: H21-11-001). Patients' background characteristics, clinical data, and mortality rates were examined. We previously reported the first registry of the Fukuoka University Hospital Lung Transplantation Program (2005–2015) in 2016[5]. To compare the recent trends of the program, the study cohort was divided into two groups (2005–2015, cohort 1 and 2016–2021, cohort 2). Baseline characteristics and outcomes were compared between the two groups.

Statistical Analysis

All statistical analyses were performed using StatMate IV for Windows (ATMS, Tokyo, Japan). Continuous data are presented as mean ± standard deviation and compared using the Student's unpaired t-test. Categorical variables are expressed as frequencies and percentages and compared using the Fisher's exact test. Survival time was calculated as the period from the time of transplantation until the patient's death, with the patients right-censored at the last contact. The Kaplan-Meier method was used for survival curve analysis, and the differences between the survival curves were analyzed using the log-rank test. A univariate analysis was performed for each clinical parameter. A P value of less than .05 was considered statistically significant.

Results

The number of patients who registered for CLT and the number who received lung transplantation (cadaveric and living related) at our institution each year between 2005–2021 are shown in Figure 1. Since the revision of the Japanese Organ Transplant Law in 2010, the number of registrations and lung transplantations has been on the rise. Baseline demographics and preoperative characteristics for all candidates of cohort 1 and cohort 2 are summarized in Table 1. The cohort's average age was 46.6 ± 10.9 years (range: 17–59) and included 77 males (59.6%). The blood type of the candidates was as follows: A, 56 (43.4%); O, 34 (26.3%); B, 28 (21.7%); AB, 11 (8.5%). Indications for lung transplantation were interstitial lung disease (ILD) in 79 patients (61.9%), graft versus host disease (GVHD) in 13 patients (10%), chronic obstructive pulmonary disease (COPD) in 12 patients (9.3%), lymphangioleiomyomatosis (LAM)

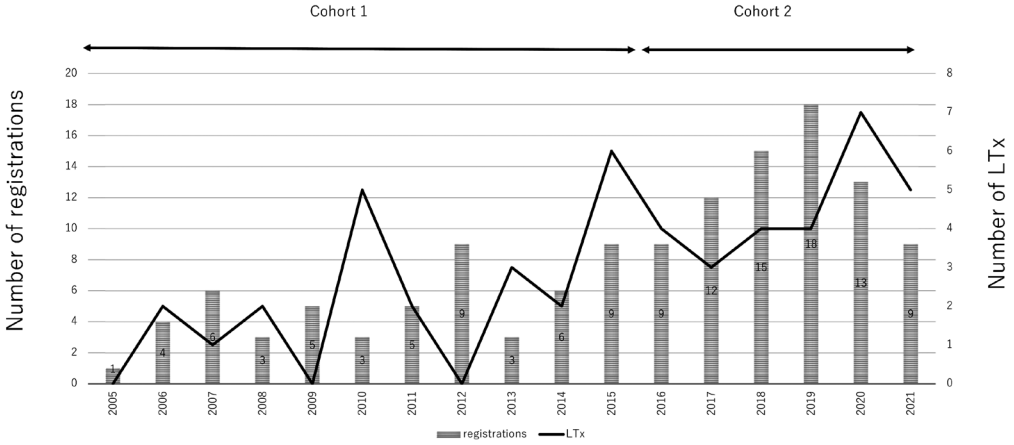


Figure 1. The annual number of patients newly registered in JOTN and recipients who underwent lung transplantation. Ltx, lung transplantations.

Table 1. Characteristics of cadaveric lung transplant candidates between 2005 and 2021

Characteristics	Total (n = 129)	Cohort 1; 2005–2015 (n = 52)	Cohort 2; 2016–2021 (n = 77)	*P* value
Average age (years) (range)	46.6 ± 10.9 (17–59)	45.5 ± 12.1 (17–59)	47.8 ± 9.5 (18–59)	.24
Male sex	77 (59.6%)	33 (63.4%)	44 (57.1%)	.58
Blood type				.45
A	56 (43.4%)	25 (48.0%)	31 (40.2%)	
B	28 (21.7%)	8 (15.3%)	20 (25.9%)	
AB	11 (8.5%)	6 (11.5%)	5 (6.7%)	
O	34 (26.3%)	13 (25.0%)	21 (27.2%)	
Diagnosis				.72
Interstitial lung disease (ILD)	79 (61.2%)	32 (61.5%)	47 (61.0%)	
Chronic obstructive pulmonary disease (COPD)	12 (9.3%)	5 (9.6%)	7 (9.0%)	
Lymphangioleiomyomatosis (LAM)	10 (7.7%)	6 (11.5%)	4 (5.1%)	
Graft versus host disease (GVHD)	13 (10.0%)	3 (5.7%)	10 (12.9%)	
Infectious lung disease	9 (6.9%)	4 (7.6%)	5 (6.7%)	
Others	6 (4.6%)	2 (3.8%)	4 (5.1%)	
Average waiting time (days) (range)	600.5 ± 558.8 (9–4050)	634.3 ± 714.5 (29–4050)	580.9 ± 433.1 (9–1998)	.59
Outcomes				
died while waiting	51 (39.5%)	23 (44.2%)	25 (32.4%)	
transplanted	45 (34.8%)	19 (36.5%)	19 (24.6%)	
awaiting	33 (25.5%)	10* (19.2%)	33 (42.8%)	

Values are the number of cases (percentage) or mean ± standard deviation. *Seven underwent lung transplantation and 3 died during cohort 2.

in 10 patients (7.7%), and infectious lung disease in 9 patients (6.9%). The average wait time before transplantation was 600.5 ± 558.8 days (range: 9–4050). Fifty-one (39.5%) candidates died while on the waiting list before receiving lung transplantation, and 45 (34.8%) candidates were successfully bridged to transplantation. Thirty-three (25.5%) candidates are still waiting for lung transplantation at the time of this report. There were no significant differences in the candidates' characteristics between the two cohorts.

A total of 45 patients underwent CLT, while LDLLT was performed in five patients during the study period. Of the 45 patients who underwent CLT, the most common primary diagnosis was ILD (n = 23, 51.1% overall; n = 9, 47.3% in cohort 1; n = 14, 53.8% in cohort 2). LAM accounted for 13.3% of the patients (n = 6, overall; n = 4, 21% in cohort 1; n = 2, 7.6% in cohort 2). Six patients (13.3%) had infectious lung disease (n = 1, 5.2% in cohort 1; n = 5, 19.2% in cohort 2) (Table 2). The average age at the lung transplantation was 48.5 ± 11.4 years (range: 17–62), and more than half of the patients were male (n = 30, 66.6%). There were no significant differences between the two cohorts. The waitlist time for the patients in cohort 2 was significantly longer than that in cohort 1 (515.3 ± 383.0 days vs. 864.7 ± 592.3 days, $P = .016$). Twenty-nine (64.4%) patients underwent unilateral CLT, and 16 (35.5%) patients underwent bilateral CLT. Bilateral CLT was performed at a higher frequency in cohort 2 compared to cohort 1 (13 vs. 3, $P = .04$). The median operative time and total ischemic time showed no significant difference between the two cohorts. The median length of stay in the intensive care unit (ICU) was 12.0 ± 9.0 days (range: 3–52). There was a statistically significant difference in the length of ICU stay between the two cohorts (15.7 ± 10.9 days in cohort 1 vs. 9.5 ± 6.5 days in cohort 2, $P = .04$). Although there was no statistically significant difference in the median hospital stay between the two cohorts, the stays were shorter in cohort 2 compared to cohort 1 (84.1 ± 58.8 vs. 209.9 ± 396.4). The 30-day and 1-year mortality rates were 5.2% and 15.8% for cohort 1 and 0% and 11.5%

Table 2. Characteristics of deceased-donor lung transplant recipients between 2005 and 2021

	Total (n = 45)	Cohort 1; 2005–2015 (n = 19)	Cohort 2; 2016–2021 (n = 26)	*P* value
Average age (years) (range)	48.5 ± 11.4 (17–62)	46.9 ± 14.3 (17–62)	49.6 ± 9.0 (27–62)	.47
Male sex	30 (66.6%)	12 (63.1%)	18 (69.2%)	.66
Diagnosis				.40
Interstitial lung disease (ILD)	23 (51.1%)	9 (47.3%)	14 (53.8%)	
Chronic obstructive pulmonary disease (COPD)	4 (8.8%)	1 (5.2%)	3 (11.5%)	
Lymphangioleiomyomatosis (LAM)	6 (13.3%)	4 (21.0%)	2 (7.6%)	
Graft versus host disease (GVHD)	3 (6.6%)	2 (10.5%)	1 (3.8%)	
Infectious lung disease	6 (13.3%)	1 (5.2%)	5 (19.2%)	
Others	3 (6.6%)	2 (10.5%)	1 (3.8%)	
Median waiting time (days) (range)	774.1 ± 521.0 (39–2777)	515.3 ± 383.0 (39–1249)	864.7 ± 592.3 (183–2777)	.016
Procedure				.04
Single	29 (64.4%)	16 (84.2%)	13 (50.0%)	
Bilateral	16 (35.5%)	3 (15.8%)	13 (50.0%)	
Operative time (minutes)				
Single	440.7 ± 131.3 (305–770)	411.4 ± 103.6 (305–735)	476.7 ± 155.7 (315–770)	.20
Bilateral	799.0 ± 144.4 (630–1163)	720.0 ± 60.6 (655–775)	817.3 ± 153.4 (630–1163)	.11
Total ischemic time (minutes)				
Single	419.3 ± 81.7 (241–540)	426.1 ± 82.3 (242–540)	411.0 ± 83.5 (241–540)	.62
Bilateral	626.6 ± 76.3 (497–737)	662.3 ± 81.5 (576–738)	618.4 ± 76.1 (497–737)	.46
Median ICU stay (days)	12.0 ± 9.0 (3–52)	15.7 ± 10.9 (6–52)	9.5 ± 6.5 (3–37)	.04
Median hospital stay (days)	137.2 ± 264.9 (1–1503)	209.9 ± 396.4 (1–1503)	84.1 ± 58.8 (33–261)	.18
Mortality				
30-day mortality	1 (2.2%)	1 (5.2%)	0	
1-year mortality	6 (13.3%)	3 (15.8%)	3 (11.5%)	

Values are the number of cases (percentage) or mean ± standard deviation.

for cohort 2, respectively. As shown in Table 3, the most common cause of death was infection (38.4% in cohort 1; 80% in cohort 2). The 3-year and 5-year survival rates for the overall cohort were 73.3% and 57%, respectively (Figure 2). Figure 3 shows the 1-year, 3-year, and 5-year survival rates determined since 2012. At the beginning of the program, the 1-year, 3-year, and 5-year survival rates were 58.3%, 46.7%, and 46.7%, respectively. The latest data of these survival rates were 85.9%, 73.7%, and 57%, respectively. Although 1- and 3-year survival has increased significantly over the past 9 years, the 5-year survival rate showed only a modest increase.

Five LDLLTs were performed during the study period (Table 4). Three patients underwent single LDLLT and two underwent bilateral LDLLT. Two of the five patients died due to primary graft dysfunction and chronic heart failure.

Table 3. Causes of death for deceased-donor lung transplant recipients between 2005 and 2021 (n = 18)

	Cohort 1; 2005-2015			Cohort 2; 2016-2021		
	0–30 days	31–365 days	>1year	0–30 days	31–366 days	>1year
Infection		1	4		2	2
Chronic rejection			3		1	
Multiple-organ failure	1		1			
Myocardial infarction			1			
Malignancy		1	1			

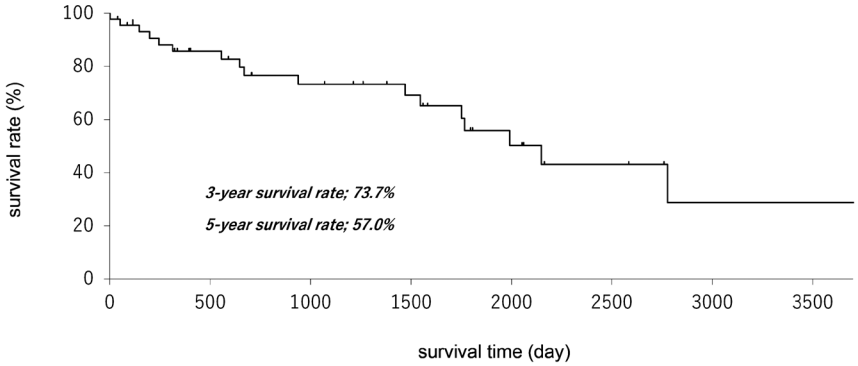
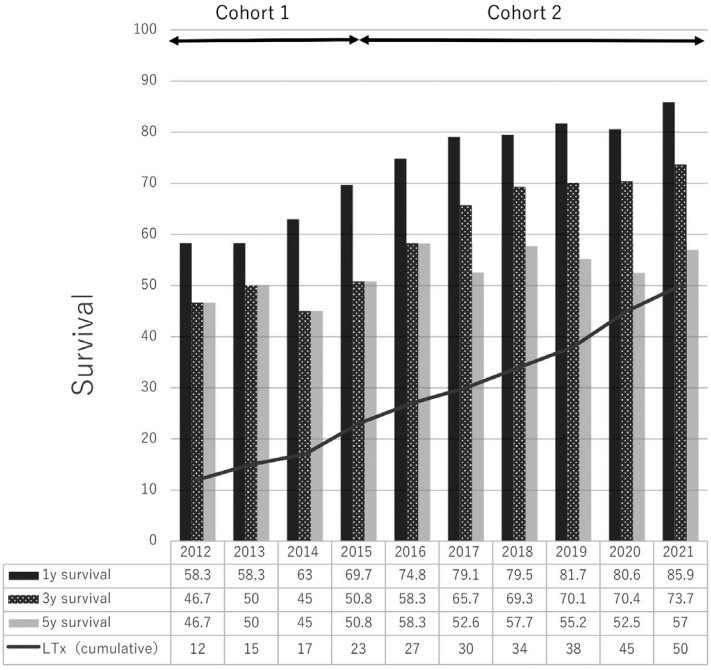


Figure 2. Kaplan-Meier survival curve for recipients who underwent CLT.



	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
1y survival	58.3	58.3	63	69.7	74.8	79.1	79.5	81.7	80.6	85.9
3y survival	46.7	50	45	50.8	58.3	65.7	69.3	70.1	70.4	73.7
5y survival	46.7	50	45	50.8	58.3	52.6	57.7	55.2	52.5	57
LTx (cumulative)	12	15	17	23	27	30	34	38	45	50

Figure 3. The cumulative number of recipients who underwent lung transplantation, and the 1-year, 3-year, and 5-year survival rates of those at the end of each year. Ltx, lung transplantations.

Table 4. Characteristics of living-donor lung transplantation patients (n = 5)

Case	Age (y)	Sex	Indication for LTx	Procedure	Cohort	Survival	Cause of death
1	4	Male	Graft versus host disease- Bronchiolitis obliterans	SLDLLTx	I	Alive	-
2	30	Female	Lymphangioleiomyomatosis	SLDLLTx	I	Alive	-
3	48	Female	Drug-induced IP	SLDLLTx	I	Dead	Primary graft dysfunction
4	20	Female	IP associated with collagen vascular disease	BLDLLTx	I	Dead	Chronic heart failure
5	52	Male	IIPs	BLDLLTx	II	Alive	-

LTx, Lung transplantation; IP; Interstitial pneumonia; IIPs, Idiopathic interstitial pneumonias; SLDLLTx, Single living-donor lobar lung transplantation; BLDLLTx, Bilateral living-donor lobar lung transplantation.

Discussion

Our study reveals that the number of patients registered in the JOTN and the number of CLT recipients in the Lung Transplant program of Fukuoka University Hospital has been increasing steadily. With increasing experience over the past 16 years, there has been an improvement in the postoperative course at our program when comparing the patient outcomes before (cohort 1) and after (cohort 2) 2015. The duration of ICU stay and hospital stay were shorter in cohort 2 compared with cohort 1. Moreover, the incidence of complications was lower in cohort 2 compared with cohort 1, as reflected by the 30-day and 1-year mortality rates. The improvement in patient outcomes observed in cohort 2 might be attributed to the refinement of the surgical technique and the advances in perioperative management involving nursing care and rehabilitation. However, as shown in figure 3, the 5-year survival was not markedly improved from the beginning of the program, despite improvements in the1-year and 3-year survival outcomes. Infection was the major cause of death throughout the study period, especially in the chronic phase after CLT in our program; therefore, pulmonologists and transplant physicians need to place special emphasis on infection control. Furthermore, chronic rejection was another leading cause of death after CLT. Although re-transplantations have not yet been performed at our center, re-registration for CLT should be considered for these patients, if the age of the recipient and multi-organ functions are acceptable.

The findings from the review of our lung transplantation program highlight some differences from the data published in the ISHLT registry and from the published reports worldwide. First, the most common worldwide indications for CLT include chronic obstructive lung disease (COPD) (36%), interstitial lung disease (30.3%), and bronchiectasis (18.4%).[2] In our program, pulmonary fibrosis (51.1%) was the most common indication for CLT, followed by LAM (13.3%), infectious lung disease (13.3%), and COPD (8.8%). The Japanese Society of Lung and Heart-Lung Transplantation data collected between 2000–2020 show that of those who received unilateral CLT, 50.6% had interstitial lung disease, 22.8% had LAM, and 15% had COPD. For bilateral CLT, 31.6% were patients with pulmonary hypertension, 23% with ILD, 16.5% with infectious lung disease, and 9.3% with GVHD. ILD was the most frequent indication for CLT in Japan, which is not consistent with the ISHLT registry. The different genetic backgrounds among races may contribute to this discrepancy.

Second, compared to counterparts in other nations, the waiting time for CLT in our program was remarkably long due to a severe donor shortage. The average waiting time for CLT was over 750 days in our program, although it is shorter than the overall average of 800 days in Japan. The current availability of cadaveric donor lungs has not been able to meet the increasing demand of recipients. To solve this challenging problem, LDLLT has been performed conventionally in Japan. LDLLT was designed for patients who have a decline in their physical status with a life expectancy of less than a few months as an alternative to CLT more than 20 years ago.[6] We also performed five LDLLTs for patients considered too ill to await CLT. The results of LDLLT have been reported to be equal to or better than CLT.[7),8)] Recently, the global pandemic due to Coronavirus Disease 2019 (COVID-19) has resulted in a significant decline in CLT all over the world.[9),10)] Japan is no exception to this trend. Thus, LDLLT might have an increased application in candidates with severe respiratory failure.

Another unique aspect of our program was the CLT procedure performed. Because of donor shortage, more than half of the recipients receive unilateral lung transplantation in Japan as a means of sharing the limited donor lungs,[11)] while the majority (66.4%) of the patients

outside Japan undergo bilateral CLT.[2] This trend was evident in our program with over 60% of the patients in our program receiving unilateral lung transplantation. Bilateral CLT was performed only for selected patients with infection or pulmonary hypertension. Although bilateral CLT recipients have been reported to have better survival than unilateral CLT recipients,[2] we recently observed acceptable results for patient survival after CLT in our program compared to the ISHLT Registry Data. The 2017 ISHLT Registry annual report showed results similar to the present study: 1-year and 5-year survival rates for bilateral CLT were 82% and 59%, respectively.[2]

It is important to recognize that a significant number of patients could not receive lung transplantation at our program. In most countries outside Japan, organs are allocated based on blood group compatibility and the Lung Allocation Score (LAS) which represents disease severity.[12),13),14)] In Japan, in addition to the issues of donor shortage, recipients are selected in the order of waiting list based on their blood types and size matching. Therefore, the time transplant candidates spend on the waiting list at our institution is about 2–3 years regardless of disease, and the mortality rate while on the waiting list was up to 39.5% in the overall cohort and 46.4% in patients with interstitial lung disease.[15] It is critical for our program to take all measures to further increase the number of donor lungs, thereby performing enough lung transplantations to meet patients' needs and reducing the rate of waitlist mortality.

Conclusions

The patient outcomes at our lung transplant center have improved, which might reflect the experience that our surgeons, including cardiovascular surgeons, anesthesiologists, and pulmonologists have accumulated over the years. However, we are still faced with the daunting challenge of improving lung preservation therapy through infection control and immunosuppressive strategies. There is an urgency to raise public awareness about the need for organ donors.

Author Contributions:

All authors have made substantial contributions to this manuscript by conducting the research or drafting and revising the manuscript. All authors have approved this version to be published.

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(Received on January 6th, 2022; Accepted on February16th, 2022)
「The authors declere no conflict of interest.」