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Outcome of lung transplantation in elderly recipients☆,☆☆

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Abstract

Objective: Lung transplantation is a standard treatment option for patients with end-stage lung disease. Lung transplantation in the elderly is controversial due to concerns over anticipated increased surgical risks, inferior long-term outcomes and proper stewardship in allocating limited donor organs. With demographic trends showing an increasing proportion of patients over 60 years old, we evaluated our outcomes with lung transplantation in this older cohort. **Methods:** Between January 1990 and July 2009, 142 patients underwent lung transplantation at our institution. A total of 15 patients receiving heart/lung transplantation and one patient declining research participation were excluded. As many as 126 patients were analyzed in two groups: $<$60 and $\geq$60 years old. **Results:** There were 65 females (52%) and 61 males (48%). A total of 53 patients (42%) underwent bilateral sequential lung transplantation and 73 patients single-lung transplantation (58%). Median age at transplantation was 55.3 years (range, 21.6—73.1 years) with 94 patients $<$60 years (75%) and 32 patients $\geq$60 years (25%). Median follow-up was 4.3 years (range, 0—17.8 years). Overall survival at 30 days was 93.7% with no difference between age groups ($p = 0.95$). There was no difference between the groups for in-hospital, postoperative complications ($p = 0.86$), or unplanned readmission rates within 90 days of the hospitalization ($p = 0.26$). Postoperative pulmonary function (forced expiratory volume in 1 s (FEV1) % predicted) at transplant, 4 weeks, 3 months, and 6 months after transplantation was not different between groups ($p = 0.93$). No difference in long-term survival was observed ($p = 0.59$), with 5-year survival of 52.2% for patients $<$60 years and 47.3% for patients $\geq$60 years. Overall, 20 patients developed bronchiolitis obliterans syndrome and 13 posttransplant lymphoproliferative disease, which was not statistically different between age groups ($p = 0.87$, $p = 0.37$, respectively). **Conclusion:** Increased age of 60 years and greater, in highly selected patients, does not appear to have a significant impact on the short- or long-term outcome in patients undergoing lung transplantation. Judicious selection of older patients, who are otherwise excellent candidates for lung transplantation, remains a reasonable option.

Keywords: Lung transplantation; Elderly; Survival; Treatment outcome

1. Introduction

Since its introduction in the early 1980s, lung transplantation (LTx) has become a standard treatment option for patients with progressive end-stage lung disease. The most frequent indications in the United States are chronic obstructive pulmonary disease (COPD) and emphysema in 36% of patients and idiopathic pulmonary fibrosis in 21% [1]. These two diseases occur predominantly in older patients.

LTx in the elderly is, however, controversial. Risk and long-term outcome in this patient cohort has been anticipated to be inferior to a younger patient population. Efforts to ensure the proper stewardship of the very limited donor organ resource have resulted in recipient advanced age being considered as at least a relative and, in some cases, an absolute exclusion criterion. Nevertheless, the changing age demographics in the industrialized countries demonstrate a phenomenon of an ever-increasing fraction of people 60 years of age and older. The convergence of an increasing demand for LTx in a population with an increasing proportion of older potential lung-transplant recipients has led us to evaluate our outcomes with LTx in this elderly population.

2. Material and methods

Patients were identified from the prospectively maintained lung-transplant program database. Between 1 January

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1990 and 31 July 2009, 142 patients underwent LTx at our institution. Of these, 15 patients received combined heart/lung transplantation and one patient declined participation in research; these patients were excluded from analysis. Therefore, 126 patients were analyzed and assigned to two groups based on age at transplantation: <60 and ≥ 60 years old.

Data are presented as median and range for continuous variables, and as frequency and percentage for discrete variables. Baseline patient characteristics, intraoperative complication rates, perioperative complication rates, and length of stay (LOS) were compared between the two age groups using the Wilcoxon rank-sum test, Pearson's chi-square test, or Fisher's exact test, as appropriate. Linear regression was used to measure the difference between age groups for hospital LOS (log-transformed), adjusting for type of transplant (single or bilateral) and use of cardiopulmonary bypass (yes/no).

The renal function of patients was assessed via serum creatinine (SCr) levels and the estimated glomerular filtration rate (GFR). Data of serum creatinine levels were collected at the time of transplantation, at 1 and 5 years after transplantation, as well as at last follow-up. Due to a change in creatinine assays at our institution, all SCr levels before October 2006 were standardized (standardized SCr = 1.092*Mayo Clinic SCr − 0.265) [2,3]. The estimated GFR was calculated with the Modification of Diet in Renal Disease (MDRD) Study equation, re-expressed for standardized SCr [4]. Repeated-measures mixed models using restricted maximum likelihood (REML) estimation were used to model log(SCr) and log(MDRD). Log transformations were needed to at least approximate the model assumptions. An unstructured correlation structure was used, which estimates a different correlation for every pair of time points (at time of transplantation, 1 year, and 5 years following LTx). Fixed effects were included for time and age group (≥ 60 years vs <60 years). Interactions between time and age were investigated and none were significant, and hence were removed from the models. Thus, only main effects were used for time and age inferences.

Pulmonary function (forced expiratory volume in 1 s (FEV1): % predicted, original scale) after transplantation was analyzed using mixed models, as above, using the time points of time of transplantation, 1 month, 3 months, and 6 months after LTx. Only main effects for time and age were ultimately kept.

Kaplan–Meier methodology was used for the outcomes of overall patient survival, 30-day survival, 90-day survival, and survival free of unplanned readmission (within 90 days of discharge), acute rejections, bronchiolitis obliterans syndrome (BOS), posttransplant lymphoproliferative disease (PTLD), hemodialysis, and kidney transplant. Survival or cumulative incidence estimates at specific follow-up times are provided. Log-rank tests were used to compare the age groups for these survival outcomes. A p-value <0.05 was considered as the threshold for statistical significance. The Mayo Clinic College of Medicine Institutional Review Board approved this study.

3. Results

There were 65 women (51.6%) and 61 men (48.4%) in the study sample, of which 53 (42.1%) underwent bilateral lung transplantation (BLTx) and 73 (57.9%) single-lung transplantation (SLTx). Median age at transplantation was 55.3 years (range, 21.6–73.1 years) with 94 patients <60 years (74.6%) and 32 patients ≥ 60 years (25.4%). In the group of patients, who were 60 years and older, 12 of 32 patients were older than 65 years (37.5%).

Twelve (37.5%) of the patients 60 years and older received a BLTx, and 20 (62.5%) an SLTx, while 41 (43.6%) of the younger group received a BLTx and 53 (56.4%) an SLTx, respectively. The median body mass index (BMI) overall was 24.2 kg m^{-2} (range, 14.8–34.3 kg m^{-2}), being slightly yet statistically significantly lower in the younger group ($p = 0.02$). A total of 35 patients (27.8%) were never smokers,

Table 1. Patient characteristics.

Variable	Overall ($n = 126$)	Age < 60 ($n = 94$)	Age ≥ 60 ($n = 32$)	p-value
Gender				0.840
Male	61 (48.4%)	46 (48.9%)	15 (46.9%)	
Female	65 (51.6%)	48 (51.1%)	17 (53.1%)	
Age (years; median (range))	55.3 (21.6–73.1)	52.2 (21.6–59.8)	64.0 (60.3–73.1)	–
BMI (kg m^{-2}; median (range))	24.2 (14.8–34.3)	23.3 (14.8–34.3)	25.5 (18.9–32.9)	0.017
Transplant type				0.545
DLTx	53 (42.1%)	41 (43.6%)	12 (37.5%)	
SLTx	73 (57.9%)	53 (56.4%)	20 (62.5%)	
Underlying lung pathology				0.0502
Emphysema/COPD	42 (33.3%)	27 (28.7%)	15 (46.9%)	
Idiopathic pulmonary fibrosis	26 (20.6%)	15 (16.0%)	11 (34.4%)	
Primary pulmonary hypertension	6 (4.8%)	6 (6.4%)	0 (0.0%)	
Emphysema/Alpha-1-antitrypsin deficiency	23 (18.3%)	20 (21.3%)	3 (9.4%)	
Cystic fibrosis	5 (4.0%)	5 (5.3%)	0 (0.0%)	
Lymphangioleiomyomatosis	4 (3.2%)	4 (4.3%)	0 (0.0%)	
BOOP	5 (4.0%)	5 (5.3%)	0 (0.0%)	
Secondary pulmonary hypertension	5 (4.0%)	5 (5.3%)	0 (0.0%)	
Pulmonary fibrosis due to connective tissue disease or other etiology	10 (7.9%)	7 (7.5%)	3 (9.4%)	

BOOP: Bronchiolitis obliterans organizing pneumonia.

while 91 patients (72.2%) had a prior smoking history with a median of 30 pack-years (range, 1–120). By protocol, all smokers had ceased smoking for at least 6 months prior to being listed for LTx and were monitored for compliance with regular surveillance cotinine levels. Patient characteristics, including the diagnostic indications for transplantation for the two age groups, are summarized in Table 1.

There were 21 patients (16.7%) who had prior sternotomy or ipsilateral thoracotomy prior to transplantation. The preoperative median FEV1 was 26% predicted (range, 5–98% predicted) and the median of preoperative mean pulmonary artery pressure was 27 mm Hg (range, 11–77 mm Hg).

Overall, in 106 patients (84.1%), there were no intraoperative complications. Cardiopulmonary bypass (CPB) was avoided during transplantation in 100 patients (79.4%). In 14 patients, the implementation of CPB was planned preoperatively, based on the preoperative evaluation of the patients (11.1%), while in 12 patients (9.5%), it was used due to intraoperative difficulties with high pulmonary artery pressures or impaired oxygenation. In addition to unplanned CPB implementation, intraoperative complications included institution of extracorporeal membrane oxygenation (ECMO) in two patients (1.6%), cardiac arrest with successful cardiopulmonary resuscitation in two patients (1.6%), intra-aortic balloon pump (IABP) use in one patient (0.8%), and intraoperative death in one patient due to severe hemodynamic instability (0.8%), as well as three patients (2.4%) with other lesser complications. Some patients suffered from a combination of these complications, which is reflected by the cumulative percentage of >100%. There were 13 patients in the younger cohort with intraoperative complications (13.8%), and seven in the older group (21.9%). The difference was not statistically significant ($p = 0.28$). Moreover, comparison of the two age groups by transplantation type did not show a statistically significant difference in intraoperative complications for BLTx ($p = 0.70$) or SLTx ($p = 0.25$).

Analysis of postoperative complications for those patients, who survived the surgical procedure, showed that complications occurred in 54 of the patients in the younger group (58.1%) and in 18 of the patients ≥60 years (56.3%; $p = 0.86$). Postoperative pulmonary complications included persistent air leak/pneumothorax of >7 days (15/125; 12.0%), pulmonary infiltrates/pneumonia (14/125; 11.2%), primary graft dysfunction (3/125; 2.4%), ECMO requirement (2/125; 1.6%), pleural effusion (1/125; 0.8%), acute rejection (2/125; 1.6%), or bronchial dehiscence (1/125; 0.8%). Nonpulmonary postoperative complications included atrial fibrillation (23/125; 18.4%) or other arrhythmias (6/125; 4.8%), reintubation (13/125; 10.4%), reoperation (8/125; 6.4%), hemidiaphragm paralysis (5/125; 4.0%), acute renal failure requiring hemodialysis (4/125; 3.2%), neurological events such as acute stroke (2/125; 1.6%) or seizure (1/125; 0.8%), and wound infection (2/125; 1.6%). Nine patients died postoperatively during their hospitalization (7.2%). Of these, two deaths occurred in the older age group (6.3%), while seven deaths were in the group younger than 60 years (7.5%). Causes of death included primary graft failure/reperfusion injury in four patients, acute respiratory failure with multiorgan failure in three, pneumonia in one, and disseminated intravascular coagulopathy in one patient.

Excluding the perioperative deaths, the median length of stay (LOS) in the intensive care unit after transplantation was 5 days (range, 1–93 days) for the patients younger than 60 years and 3 days for the patients 60 years of age and older (range, 1–94 days) ($p = 0.001$). Mechanical ventilation was administered for a median of 2 days (range, 0–92 days) in the younger group and for a median of 1 day in the older age group (range, 0–3 days) ($p < 0.001$). The median hospital LOS for the patients of 60 years and older was 14.5 days (range, 4–74 days). This was slightly longer for the younger patients (median 16 days, range 6–97 days) ($p = 0.006$). The difference between the age groups for hospital LOS remained after adjusting for type of transplantation (BLTx or SLTx) and intraoperative use of CPB ($p = 0.004$).

Data for unplanned readmission within 90 days after dismissal from the hospital were available for 115/116 patients (99.1%). The overall unplanned readmission rate within 90 days of dismissal was 51.3%. In the group of patients older than 60 years of age, 56.7% were readmitted to the hospital, while 49.4% of patients younger than 60 years were, with no statistical difference between the two age groups ($p = 0.258$). Reasons for readmission included pneumonia in 17/59 patients (28.8%), decline in lung function in 8/59 (13.6%), pneumothorax in 7/59 (11.9%), atrial fibrillation or other arrhythmia in 5/59 (8.5%), mental status changes in 5/59 (8.5%), minor gastrointestinal discomfort such as nausea or dehydration in 5/59 (8.5%), empyema in 2/59 (3.4%),

Table 2. Renal and graft function results.

Variable	Time	N	Overall median (min, max)	Age < 60 median (min, max)	Age ≥ 60 median (min, max)	Age p-value[a]	Time p-value[a]
SCr, mg dl^{-1}	Transplant	126	0.7 (0.3, 1.3)	0.7 (0.3, 1.2)	0.7 (0.4, 1.3)	0.945	<0.001
	1 year	95	1.3 (0.4, 3.5)	1.3 (0.4, 3.5)	1.3 (0.6, 2.2)		
	5 years	26	1.6 (0.6, 4.2)	1.6 (0.9, 4.2)	1.0 (0.6, 1.4)		
Creatinine clearance, ml/min/1.73 m^2	Transplant	126	101 (49, 232)	103 (57, 232)	100 (49, 162)	0.096	<0.001
	1 year	95	51 (13, 163)	52 (13, 163)	45 (23, 101)		
	5 years	26	38.5 (11, 100)	38 (11, 97)	69 (38, 100)		
FEV1, % predicted	Transplant	126	26 (5, 98)	26 (5, 98)	25.5 (10, 77)	0.931	<0.001
	1 month	107	61 (11, 122)	60 (11, 122)	61 (32, 95)		
	3 months	110	63.5 (17, 117)	63 (17, 112)	64 (36, 117)		
	6 months	106	61 (22, 136)	61 (22, 120)	69 (33, 136)		

[a] From repeated-measures model with main effects for age and time (outcomes: log(SCr), log(creatinine clearance, and FEV1% predicted).

wound infection in one patient (1.7%), and other miscellaneous reasons (27.1%). Some patients had more than one reason for unplanned readmission, which is reflected by the cumulative percentage being >100%.

3.1. Renal function

Renal function results are provided in Table 2. No age effects were observed for either SCr ($p = 0.95$) or creatinine clearance ($p = 0.10$). Six patients required hemodialysis after lung transplant, five of whom were patients younger than 60 years as well as one patient in the older age group. The 5- and 10-year cumulative incidence estimates were 6.0% and 23.1%. The 5-year incidence for those younger than 60 years versus those 60 years or older was 6.2% versus 3.1%. The age groups were not significantly different in terms of incidence of hemodialysis requirement ($p = 0.83$). Six patients underwent kidney transplantation after LTx (median time = 16.4 years), all of whom were patients younger than 60 years. The 5- and 10-year cumulative incidence estimates were 3.0% and 25.6%. The 5-year incidence for those younger than 60 years versus those 60 years or older was 4.7% versus 0.0%. The age groups were not significantly different for the incidence of kidney transplantation ($p = 0.49$).

3.2. Graft function

Pulmonary function was compared by means of FEV1 (% of predicted) between the two age groups at the time of transplantation, 1 month, 3 months, and 6 months after transplantation (Table 2). The age cohorts were not significantly different ($p = 0.93$).

Other endpoints analyzed during the follow-up period were events of acute rejection, BOS, and PTLD. One year after transplantation, overall 76.4% of patients were free of acute rejection, and 55.3% at 5 years. Rejection-free survival for the patients younger than 60 years was 75.3% at 1 year and 54.6% at 5 years, compared with 79.9% and 55.3%, respectively, in the older population ($p = 0.54$). Overall, 20 patients (15.9%) developed BOS. BOS-free survival at 1 year was 100% and 74.4% at 5 years, with no statistical significant difference between the age groups ($p = 0.87$): at 5 years 74.4% of the younger patients and 74.3% of the older patients were BOS-free. There were 13 patients, who developed posttransplant lymphoproliferative disease with no difference found between the two age cohorts ($p = 0.37$). At 1 year, 91.6% of patients were PTLD free and 89.4% after 5 years.

3.3. Patient survival

Overall 30- and 90-day patient survival after LTx was 93.7% and 91.3%, with no adverse affect, based on the age at transplantation ($p = 0.95$ and $p = 0.91$, respectively). Comparing the two age groups by transplantation type, there were no 30-day and 90-day survival differences for BLTx ($p = 0.44$ and $p = 0.34$, respectively) and SLTx ($p = 0.77$ and $p = 0.53$, respectively).

Overall 5-year and 10-year survival was 51.3% and 21.2%, respectively (Fig. 1). No adverse effect of increased age was observed when considering the entire follow-up time

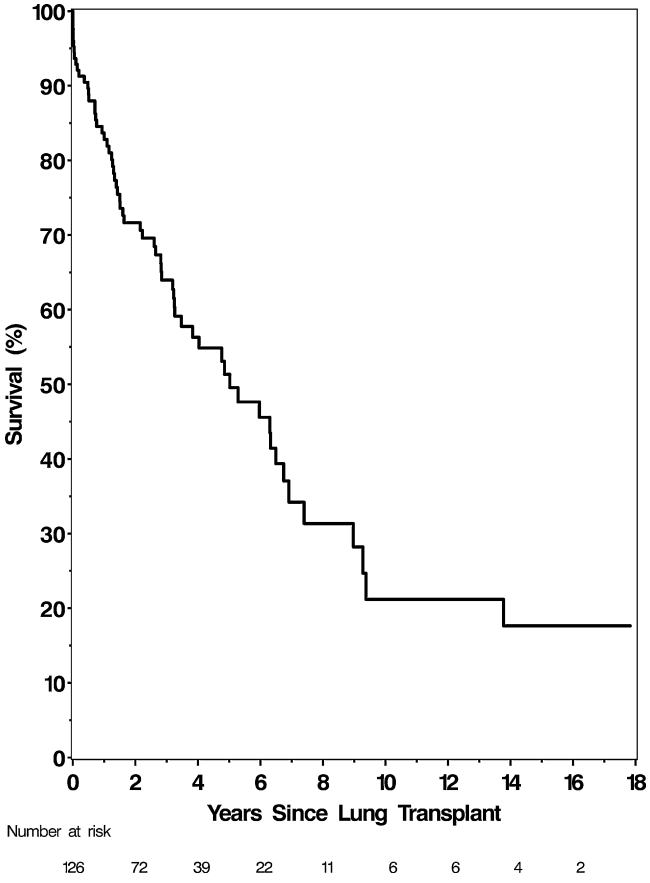

Fig. 1. Overall survival.

($p = 0.95$), with 5-year survival of 52.2% for patients <60 years old and 47.3% for patients ≥60 years old (Fig. 2).

4. Discussion

LTx in elderly patients remains contentious in the face of a significant shortage of suitable donor organs. Nevertheless, the demographic trends predict a continued progressive 'aging' of the population with a resultant increased proportion of patients over the age of 60 years seeking LTx to treat their end-stage lung diseases. Currently, as much as one-quarter of lung recipients at our institution are 60 years and older.

The age distribution of lung recipients reported in the 26th Transplantation Report of the registry of the International Society for Heart and Lung Transplantation (ISHLT) shows that the fraction of patients of 60 years or older was 35% in 2008, compared with 15% in 1998 [1]. For the two indications most commonly treated by LTx, notably COPD and idiopathic pulmonary fibrosis, recent reports confirm the increasing age of lung-transplant recipients with these diagnoses [5,6]. In the United States, age is now an important factor used in the equation used to allocate donor lungs for transplantation. Furthermore, early analysis of the results of converting to the 'lung allocation score' has shown that older patients make up an increasing proportion of listed candidates and there is a trend toward an increasing age of lung-transplant recipients. Patients over the age of 65

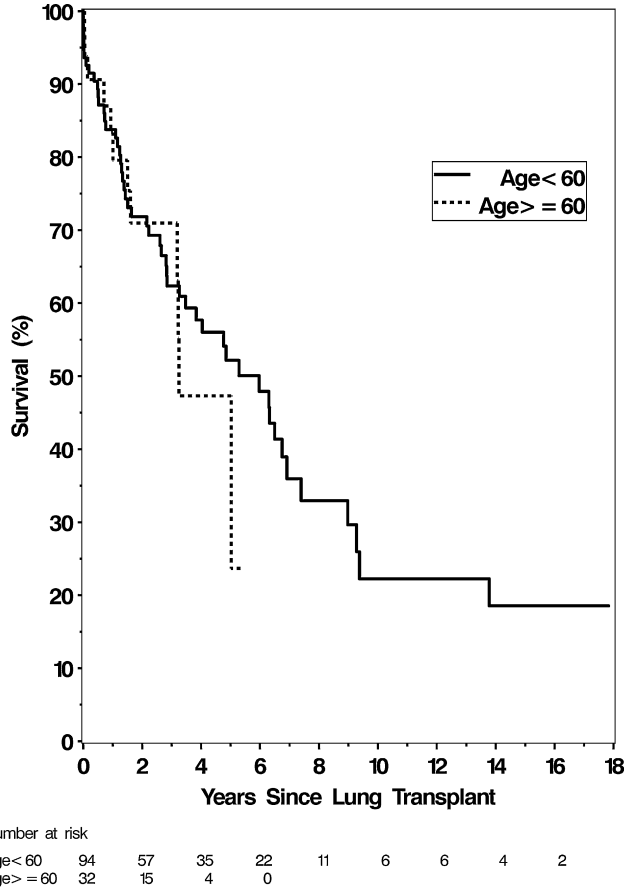

Fig. 2. Survival by age.

years are the only age group that has increased in both raw numbers and percentage of candidates since the late 1990s, making up over 9% of listed candidates for LTx in the United States in 2007 [7,8].

Compared with younger patients, this highly selected population has acceptable survival and outcome with respect to pulmonary graft function, which agrees with reports by other investigators [9,10]. Smith and colleagues found no significant survival difference between recipients of 60 years of age or older ($n = 52$) when compared with patients younger than 60 years ($n = 130$) with a 1-year survival of 86.0% compared with 88.9% and a 5-year survival of 54.7% compared with 61.0%, respectively [9]. This report by Smith and colleagues, as with our report, has the limitation of being a single-center series that may be underpowered to identify a true survival difference. In the 26th ISHLT registry report, survival rates differed significantly by recipient age, reporting 1-year survival rates of 72% for patients aged older than 65 years compared with 80% for patients younger than 50 years, and a 5-year survival of 37% compared with 56% [1].

Nevertheless, survival in our program's cohort was not impacted by older recipient age for both bilateral sequential and single LTx. Fischer and colleagues studied the outcome of a subset of 18/248 lung recipients 60 years of age or older, of which 11 patients underwent unilateral transplantation and seven underwent bilateral transplantation, with 1-year survival of 73% versus 43%, respectively, concluding that unilateral transplantation should be preferred in this older population [11]. The authors reported a reduced 1-year survival rate of 61% for patients 60 years of age or older compared with 82% of patients younger than 60 years ($p < 0.05$). However, larger studies reported that BLTx is not associated with higher mortality in patients older than 60 years and that this patient population should therefore not be excluded from consideration for BLTx [12–14].

With respect to in-hospital complications and readmission rates, there seems to be no adverse effect of an increased age, which may however be due to the rather small sample size in this study. Yet, our findings are consistent with reports of acceptable associated morbidity at other institutions [9,10].

Chronic kidney disease is a frequent sequela in nonrenal solid organ transplantation and is attributable to multiple factors such as pre-transplantation renal function, patient age and underlying comorbidities, clinical status during perioperative period, and long-term calcineurin inhibitor exposure [15–17]. The renal function documented in the population of this limited study nevertheless corresponds to findings in the literature. Data of the ISHLT registry report indicated renal dysfunction in 25% of 1-year survivors with a creatinine level of <2.5 mg dl^{-1} in 17.4% and >2.5 mg dl^{-1} in 5.9%. Renal replacement therapy by means of chronic dialysis was used in 1.6% and by renal transplantation in 0.1% [1]. In 5-year survivors, the prevalence of renal dysfunction increased to 36.6% with a creatinine level of <2.5 mg dl^{-1} in 24.1% and >2.5 mg dl^{-1} in 9.0%, respectively. Chronic hemodialysis was necessary in 3.0% and renal transplantation in 0.5% of the 5-year survivors. Mason and colleagues evaluated the prevalence of renal failure requiring hemodialysis after transplantation in a retrospective analysis of 425 patients after LTx [16]. Prevalence of hemodialysis at 5 years after transplantation was 9%, and 9 years after transplantation was 19%. The limitation of this study, in this regard, is in its retrospective nature and the use of an estimated creatinine clearance based on the modification of diet in renal disease study calculation [18]. The equation does not take into account weight, and hence may underestimate the GFR for patients with a higher body weight, and overestimate it for underweight patients. However, the measurement of creatinine clearance was inconsistent and has changed in our institution over the 19-year period of this study. Therefore, the estimated GFR has been used in all patients for consistency and comparability of data.

Certain end-stage lung diseases do have differing distributions according to age. While idiopathic pulmonary fibrosis and COPD are usually diagnosed in patients in their sixth to eighth decade, lung failure due primarily to pulmonary arterial hypertension and cystic fibrosis is more commonly found in younger population cohorts. In studies comparing outcomes based on age of the lung-transplant recipient, it is expected to have these same differences observed in the age-based cohorts. As with any comparisons based on multiple differing primary diagnoses, analysis of overall outcome data must take into account the expected survival outcomes for each of these disease groups. As an example, it is recognized that patients receiving LTx for pulmonary arterial hypertension have both a higher early postoperative morbidity and mortality and also demonstrate the highest 1-year conditional survival following transplanta-

tion. That is to say, those pulmonary arterial hypertension patients who survive for at least 1 year have the best long-term posttransplant survival [1].

The selection process used when considering so-called 'elderly' patients for LTx is not, at least initially, different from the process used for 'younger' candidates. Confirming a diagnosis of end-stage lung disease that is treatable by LTx is always the first step. Subsequent testing to identify and measure the extent of other comorbidities is also routinely done for all adult lung-transplant candidates, as is the determination of psychosocial ability to manage posttransplant circumstances. Where there is a differentiation in the evaluation process of potential lung-transplant recipients is the fact that, with increasing age beyond 60 years, there is diminishing allowance for extrapulmonary comorbidities and/or psychosocial instability. Simply put, a patient, for the most part independent of his/her age, who presents with isolated lung disease, is likely to be a suitable candidate for LTx as this is the one aspect that is directly reversed by the lung-transplant process. Where age becomes a factor is the fact that, in general, with increasing age, there is usually increasing prevalence of comorbidities, which can become limiting factors in the short- and long-term success of LTx for that particular patient.

In conclusion, an increased age of 60 years and older does not appear to have a significant impact on the short- or long-term outcome in patients undergoing LTx, if patients are selected carefully. Therefore, judicious selection of older patients, who are otherwise excellent candidates for LTx, remains a reasonable option.

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