



The use of extended criteria donors decreases one-year survival in high-risk lung recipients: A review of the United Network of Organ Sharing Database

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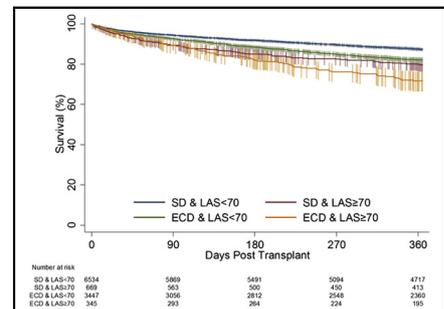
ABSTRACT

Objective: The study objective was to investigate the impact of matching donor quality to recipient severity on survival after lung transplant.

Methods: By using the Organ Procurement and Transplantation Network/United Network for Organ Sharing dataset, we analyzed lung transplant recipients from May 4, 2005, to December 31, 2012. By using adjusted Cox regressions, we identified extended criteria donors as those who had 1 or more of the following: age 65 years or more, smoking history of 20 pack-years or more, diabetes mellitus, or African-American race. All other donors were considered standard donors. Recipients were categorized by lung allocation score: lung allocation score less than 70 and lung allocation score 70 or greater. Our primary outcome was 1-year survival after lung transplantation.

Results: Of the 10,995 lung recipients, 3792 (34%) received extended criteria donor organs. Extended criteria donors were associated with an increased hazard of death (hazard ratio [HR], 1.41; 95% confidence interval [CI], 1.26-1.56; $P < .001$). One-year survival was 87% and 82% ($P < .001$) for recipients with a lung allocation score less than 70 and 80% and 72% ($P = .017$) for recipients with a lung allocation score 70 or greater who received standard donor and extended criteria donor organs, respectively. In Cox regression models, the hazard of death was increased for recipients with a lung allocation score less than 70 + extended criteria donor (HR, 1.42; 95% CI, 1.27-1.60; $P < .001$), recipients with a lung allocation score 70 or greater + standard donor (HR, 1.37; 95% CI, 1.10-1.71; $P = .005$), and was the highest for recipients with a lung allocation score 70 or greater + extended criteria donor (HR, 1.81; 95% CI, 1.40-2.33; $P < .001$) compared with recipients with a lung allocation score less than 70 + standard donor.

Conclusions: Extended criteria donors are associated with reduced 1-year survival, and recipients with a lung allocation score 70 or greater who receive extended criteria donor organs have the lowest survival. (*J Thorac Cardiovasc Surg* 2016;152:891-8)



Survival by donor quality and recipient severity with a 95% CI.

Central Message

Matching donor quality to recipient severity is critical to achieve optimal outcomes in lung transplantation.

Perspective

Lung transplantation is limited by donor shortage. The use of donors who do not meet all ideal donor criteria increases donor availability but potentially decreases survival. By using the OPTN/UNOS dataset, we showed that the use of ECDs is associated with reduced 1-year survival and that survival is the lowest in lung recipients with a LAS 70 or greater who receive an ECD organ.

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Lung transplantation remains the standard treatment for end-stage pulmonary disease. However, it is currently

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Abbreviations and Acronyms

BMI	=	body mass index
CI	=	confidence interval
CMV	=	cytomegalovirus
ECD	=	extended criteria donor
HR	=	hazard ratio
LAS	=	lung allocation score
OPTN	=	Organ Procurement and Transplantation Network
SD	=	standard donor
UNOS	=	United Network for Organ Sharing

limited by a severe shortage of usable donors. In 2013, there were 8268 brain-dead donors in the United States, but only 1922 lung transplants (Organ Procurement and Transplantation Network [OPTN] data as of February 20, 2015; <http://optn.transplant.hrsa.gov>). The ideal donor criteria, which includes ABO compatibility, age less than 55 years, clear chest radiograph, smoking history of 20 pack-years or less, arterial oxygen tension 300 mm Hg or greater on 100% oxygen with 5 cm H₂O positive end-expiratory pressure, absence of significant chest trauma, no aspiration/sepsis, no prior cardiac/pulmonary operation, no organisms on donor gram stain if prolonged intubation, no purulent secretions on bronchoscopy, and adequate size match, were drafted with the intention of selecting lungs that could tolerate the effects of ischemia–reperfusion while providing good outcomes.¹ The use of donors who deviate from these ideal criteria has allowed centers to increase the number of transplants without an apparent detriment on outcomes.^{2–5} A recent study of the OPTN/United Network for Organ Sharing (UNOS) database revealed that 56% of the lung donors used for transplants had at least 1 variance from the ideal donor criteria.⁶ However, to date there is a paucity of data on the impact of matching donor quality to recipient severity in lung transplant outcomes.

The goals of this study were to use the OPTN/UNOS database to identify donor factors that were associated with reduced post-transplant 1-year survival, to use these identified factors to define extended criteria donors (ECDs), and to evaluate 1-year survival of low- and high-risk lung recipients who received standard donor (SD) or ECD lungs. Our hypothesis is that transplanting ECD lungs into high-risk recipients would be associated with worse survival.

MATERIALS AND METHODS

We performed a retrospective analysis of 10,995 lung transplant recipients in the OPTN/UNOS Transplant Registry from May 4, 2005, to December 31, 2012. We excluded recipients aged less than 18 years, recipients of lungs from donation after circulatory determination of dead donors, retransplants, recipients on extracorporeal membrane oxygenation, recipients who received lobar transplants, and recipients with multiorgan transplants. The primary outcome was 1-year survival after lung transplantation.

Extended Criteria Donors

A series of univariate Cox hazard regressions on 1-year survival were performed on pertinent donor criteria available in the OPTN/UNOS database, including age categorized by age less than 55 years, age 55 years or more and less than 65 years, and age 65 years or more; arterial oxygen tension 300 mm Hg or less; history of smoking 20 pack-years or more; abnormal chest x-ray; purulent secretions on bronchoscopy; sex; race categorized by Caucasian, African-American, and other; diabetes mellitus; mechanism of death categorized by stroke, blunt trauma, gunshot, asphyxiation, and other; body mass index (BMI); coronary artery disease; hypertension; and ABO blood group categorized by A, B, AB, and O (Table E1). Donor factors found to be significantly associated with reduced survival in the univariate analysis were run in a stepwise Cox hazard regression model adjusted for recipient variables known to influence transplant survival (Table E2). We found that donor age 65 years or more, history of smoking 20 pack-years or more, diabetes, and African-American race were all independent risk factors for death in 1 year after transplant. Any donor who had any 1 of these identified criteria was considered an ECD. Donors who did not meet any of the criteria were considered SDs. There were missing values for identified ECD factors: history of smoking 20 pack-years or more (n = 96) and diabetes (n = 32). The percentage of missing values for at least 1 ECD factor is 1%.

Recipient Severity

Recipients were categorized according to their lung allocation score (LAS): LAS less than 70 or LAS 70 or greater. We found that only recipients with LAS 70 or greater were associated with decreased survival in 1 year, which is consistent with previous work demonstrating that a LAS 70 or greater has an increased hazard of post-transplant death.⁷

Pairing of Donor Quality With Recipient Severity

A 4-category variable was created to indicate the overall risk status of matching donor quality and recipient severity: SD and LAS less than 70, ECD and LAS less than 70, SD and LAS 70 or greater, and ECD and LAS 70 or greater.

Covariates

Covariates were variables significantly associated with reduced transplant survival and included cytomegalovirus (CMV) mismatch, mechanical ventilation, BMI, creatinine, total bilirubin, ischemic time, single lung transplant, sex, age, and diagnosis categorized by idiopathic pulmonary fibrosis, chronic obstructive pulmonary disease, cystic fibrosis, pulmonary hypertension α 1-antitrypsin deficiency, and other diagnoses. In models using LAS as a marker for recipient severity, we controlled for variables in the LAS that were independent predictors of survival, which included age, diagnosis, creatinine, total bilirubin, and mechanical ventilation, and transplant variables including CMV mismatch, single lung, and ischemic time. There were missing values for the covariates: BMI (n = 1), creatinine (n = 64), total bilirubin (n = 299), ischemic time (n = 576), CMV mismatch (n = 645), and diagnosis (n = 1). The percentage of missing values for at least 1 covariate is 12%.

Statistical Analysis

Continuous variables were expressed as mean \pm standard deviation or median and interquartile range, and categorical variables were expressed as counts and percentages. Student *t* tests were used to test continuous variables with normal distributions, and the Mann–Whitney *U* test was used for non-normal continuous variables. Categorical variables were tested using the chi-square and Fisher exact tests. Survival was evaluated using Kaplan–Meier methods and compared with log-rank tests. Kaplan–Meier survival is presented as percentage survival \pm standard error. Cox proportional hazard models were performed to assess the recipient/donor risk status in relation to time to death before and after adjusting for

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