ORIGINAL ARTICLE

Defining an extended criteria donor lung: an empirical approach based on the Eurotransplant experience¹

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Keywords

extended criteria donors, lung allocation.

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Conflicts of Interest

The authors have no conflicts of interest to disclose.

¹Presented in part at the 14th congress of the European Society for Organ Transplantation, September 2009, Paris

Received: 17 August 2010 Revision requested: 8 October 2010 Accepted: 19 November 2010 Published online: 13 December 2010

doi:10.1111/j.1432-2277.2010.01207.x

Introduction

As the number of patients referred for lung transplantation has outpaced the availability of donor organs, it is evident that donor recognition and adequate judgment of the suitability of a potential lung donor should be optimal for maximizing lung donation rates [1,2].

Lung donors are still a scarce resource; in Eurotransplant, in 2009, only 25% of all multi-organ donors were lung donors [3]. This lung donor utilization could be further improved by usage of extended criteria donors.

In Eurotransplant, there are already two well-established definitions of an extended criteria donor (ECD):

Summary

The aim of this study was to design and validate a lung donor score that reflects experts' perceived risk of allograft failure. All lung donors reported to Eurotransplant from 1999 to 2007 [N = 6080] were used to create a lung donor score. Based on observed discard rates and using multivariate regression, points were assigned for six preprocurement donor variables. Donors reported in 2008 were used to validate the score [N = 751]. All the six factors significantly predicted discard; as an example, the following donor with points: age 55-59 years: 2; compromised history: 4; smoking: 2; shadow on chest X-ray: 2; purulent secretion during bronchoscopy: 2; and Pao2/Fio2 ratio below 300 mmHg: 3. Discard rates for donors with a lung donor score of 6 points (class 1) was 18%, while 36% and 54% of the donors with a score of 7-8 (class 2) and 9 + (class 3) were discarded (P < 0.001), respectively. In addition, the donor lung score was significantly associated with 1-year survival: class 1: 91%; class 2: 80%; and class 3: 72% (P = 0.017). The lung donor score accurately reflects the likelihood of organ acceptance and predicts patient mortality, and its application at time of donor reporting may facilitate donor risk assessment and patient selection.

donors with predefined specific conditions, and donors that do not pass the standard allocation [4].

For donors with predefined conditions, a 'donor profile' procedure is used in the Eurotransplant candidate listing and selection process. These conditions include previous history of malignancy, sepsis, drug abuse, meningitis, or positive virology. During the registration of a recipient on the lung waiting list or any time thereafter, the treating physician denotes whether this particular recipient would be willing to accept an organ from a donor with any of the above listed conditions. Only patients who have given their consent for the acceptance of this type of ECD will be selected for the matching process; therefore, these lungs will only be offered to eligible recipients. This is called directional matching of an ECD.

Lungs are offered to patients on the match list in which the rank position is determined by several match criteria, including urgency status of the recipient and waiting time. If the lung offer has been rejected by at least three different centers because of donor-related medical reasons, this donor lung is considered to be an ECD lung and the standard allocation (patient-oriented offer) can be switched to rescue allocation (center-oriented offer) [5].

Despite the availability of these hands-on definitions of an ECD lung donor, there is a need for a donor quality assessment tool that can predict acceptance of a lung offer. While experience is critical in defining acceptability criteria, for donors in the gray zone between the 'ideal' lung donor and the 'unusable' lung donor, an objective donor assessment tool can help in the decision-making process of acceptance or rejection of a lung offered for transplantation [6,7].

Oto *et al.* developed a lung donor score using objective and easily available preprocurement donor factors [8]. Instead of evaluating each characteristic separately, such as donor age and chest X-ray, a combination of donor factors was used to define an ECD.

The aim of this study was not to redefine lung donor criteria, but to create and validate a lung donor score based on the Oto score, which will enable a better judgment of donor acceptability and facilitate a donor quality risk adjustment of post-transplant outcome analyses.

Patients and methods

The following five donor factors were used in the Oto score: age, smoking history, chest X-ray, bronchoscopy, and arterial partial pressure of oxygen (Pao₂)/fraction of inspired oxygen (Fio₂) ratio. This score was derived on single institution data, allowing an almost infinite use of complete clinical data. Eurotransplant hosts a multicenter registry and the lack of detailed data has hampered validation of this score. Therefore, a new donor scoring system was designed that encompassed the same five variables of the Oto score with the addition of donor history factors currently used for directional matching in Eurotransplant. (Table 1) If the donor had a history of a malignancy, sepsis, drug abuse, meningitis, or a positive virology status (HBsAg, HBcAb, HCVAb, anti-CMV), the donor was labeled 'compromised donor history'.

The adaptations to the Oto score were carried out by reclassifying the donor characteristics according to studies from Botha *et al.* and the ISHLT lung donor acceptability criteria [8,9].

Table 1.	Donor	discard	rates	for	the	derivations	set:	all	consecutive
lung donors reported in Eurotransplant in 1999–2007.									

			Not used		
Factor	Reported donors¤	Used donors‡	Donor medical reasons	Other reasons	Donor Discard rate*
Overall	6080	3380	1962	738	36.7%
Donor age (y)					
<45	3445	2036	998	411	32.9%
45–54	1713	942	601	170	39.0%
55–59	545	258	214	73	45.3%
60+	377	144	149	84	50.9%
Donor history					
Compromised†	176	43	70	63	61.9%
Uncompromised	5904	3337	1892	675	36.2%
Smoking history					
Yes	1799	909	692	198	43.2%
No	3167	1870	904	393	32.6%
NA	1114	601	366	147	37.8%
Chest X-ray					
Clear	2790	1741	813	236	31.8%
Edema	91	50	35	6	41.2%
Shadow	800	394	316	90	44.5%
Atelectasis	139	71	53	15	42.7%
Consolidation	57	26	20	11	43.5%
NA	2203	1098	725	380	39.8%
Bronchoscopy					
Clear	1167	760	330	77	30.3%
Nonpurulent	360	199	136	25	40.6%
Purulent	586	279	239	68	46.1%
Inflammation	55	23	24	8	51.1%
Visualized tumor	8	2	6	0	75.0%
NA	3904	2117	1227	560	36.7%
PO2/FiO2 (mmHg)					
>450	1216	856	262	98	23.4%
351–450	1172	759	307	106	28.8%
301–350	584	298	228	58	43.3%
<=300	1173	527	511	135	49.2%
NA	1935	940	654	341	41.0%

*Donor discard rate (due to donor-related medical reasons) is calculated as follows: number of donors that are not used for donor medical reasons/(reported number of donors – number of donors that are not used for other reasons), hence only donor-related causes are reflected, p.e., the overall discard rate is obtained by 1962/(6080– 738) = 36.7.

†The donor history is compromised in case of a malignancy, sepsis, drug abuse, meningitis, or a positive virology was registered.

‡At least one lung used for transplantation.

¤At least one lung reported.

Separate classes were created for missing values. Donor information available at the time of reporting was used.

Donor score derivation

All consecutive lung donations after brain death (DBD) reported to the registry by each of the seven Eurotrans-

plant countries during the period January 1, 1999 to December 31, 2007 were included in the study [N = 6080].

The primary study end-point was donor discard primarily related to donor medical reasons. Donors that were ultimately not used for transplantation due to recipient, logistical or other reasons would constitute a bias and were therefore not considered in this study. Unless mentioned otherwise, the term donor discard in this paper refers to the discard primarily related to donor medical reasons.

A multivariate logistic regression model allowed the assessment of the effects of donor factors on discard rate. The estimated odds ratios were used as weight factor for the donor classes, where a separate coefficient was estimated for the missing classes.

Finally, for each donor, a score was obtained by the addition of these weights (points) where a high score reflects a bad quality donor and vice versa. Hence, the assignment of points was completely empirically based: only the strength of the associations between the donor factors and the discard rate forms the basis of the lung donor score.

Donor score validation

The validation cohort consisted of all consecutive DBD lung donors reported by Eurotransplant countries during the period of January 1, 2008 to December 31, 2008 [N = 751]. Donors that were discarded for other but donor-related medical reasons were excluded.

The lung donor score calculated on the derivation cohort was applied to this validation cohort, with points assigned to donors based on six identical characteristics.

Multivariate analysis

A logistic regression model was used to test the association between the lung donor score and donor discard primary due to donor-related medical reasons.

Post-transplant outcome

The 1-year post-transplant outcome of patients transplanted in 2006 was studied using Kaplan–Meier estimates and a Cox' proportional hazards (PH) model (N = 442). The association between the lung donor score and survival was assessed in the context of the following confounding factors: recipient age, underlying lung disease, urgency status at time of transplantation, type of lung transplant (bilateral versus single), first versus retransplant, and duration of cold ischemia. All data were analyzed using the SAS software package (v6.12 SAS; Cary, NC).

Results

Donor score derivation

Study population

A total of 6080 lung donors were reported from Eurotransplant countries to the registry during the study period (January 1, 1999 to December 31, 2007). For 3380 (55.6%) donors, at least one lung was used for transplantation. Of the donors not utilized, 72.7% (N = 1962) were discarded for donor-related medical reasons; recipient-related medical reasons constituted the largest group (314, 42.5%) of nonutilization for other reasons (Fig. 1). Donor discard rate primarily due to donor-related medical reasons for this 9-year cohort was 36.7% (Table 1). Discard rates for the different donor characteristics in this validation set are depicted in Table 1.



Figure 1 Flow chart of all reported lung donors in Eurotransplant in 1999–2007.

 Table 2. Logistic regression model for the end-point donor discard.

 All consecutive lung donors reported in Eurotransplant in 1999–2007.

Factor	OR	Points*	<i>P</i> -value
Donor age (y)			
<45	1	1	<0.001
45–54	1.33	1	
55–59	1.77	2	
60+	2.68	3	
Donor history			
Compromised†	3.90	4	<0.001
Uncompromised	1	1	
Smoking history			
Yes	1.53	2	<0.001
No	1	1	
NA	1.18	1	
Chest X-ray			
Clear	1	1	<0.001
Edema	1.28	1	
Shadow	1.65	2	
Atelectasis	1.31	1	
Consolidation	1.58	2	
NA	1.23	1	
Bronchoscopy			
Clear	1	1	<0.001
Nonpurulent	1.48	1	
Purulent	1.87	2	
Inflammation	2.83	3	
Visualized tumor	5.34	5	
NA	1.26	1	
PO2/FiO2 (mmHg)			
>450	1	1	<0.001
351–450	1.26	1	
301–350	2.40	2	
<=300	2.97	3	
NA	2.35	2	

*Points are based on the regression coefficients.

+The donor history is compromised in case of a malignancy, sepsis, drug abuse, meningitis, or a positive virology was registered.

Multivariate regression model

Table 2 shows that all the six donor factors were significantly associated with donor discard (all *P*-values < 0.0001). The odds ratios obtained from the multivariate model reflect the likelihood of donor discard for each class compared with the baseline class. For example, the odds of donor discard for a donor aged 60+ years were 2.68 times greater than that of a donor under the age of 45 years, yielding 3 points.

Discard rates by lung donor score

For every donor, points were summarized to yield a total score. Patients were then grouped according to their score. Figure 2 shows the number of reported donors and the discard rate stratified by value of the lung donor score. There was a direct relationship between the value





Figure 2 Discard rate for donor-related medical reasons by lung donor score. Eurotransplant 1999–2007. Number of donors as bars, left Y-axis; discard rates as line, right Y-axis.

of the score and the likelihood that a reported lung donor was discarded for donor-related medical reasons (P < 0.0001).

Donor score validation

Study population

All consecutive lung donors reported by the Eurotransplant countries in the year 2008 were analyzed for the validation set (N = 751). For 463 (61.7%) of these donors, at least one lung was used for transplantation, while the donor discard rate primarily due to donor medical reasons was 34.1% (Fig. 3). The discard rates for each level of the six donor factors are given in Table 3.

The number of reported donors and the discard rate stratified by lung donor score are given in Fig. 4. With increasing score, the proportion of discarded donors increases (P < 0.0001).

Multivariate analysis

The logistic regression model showed that the lung donor score was strongly associated with the likelihood of donor discard (P < 0.001) (Fig. 4) After controlling for differences in donor profiles, as defined by the lung donor score, the factor donor country was not significantly associated with discard rate (P = 0.18) (data not shown).

Post-transplant outcome

Results of the both the Kaplan–Meier estimates and the Cox PH analysis showed that the lung donor score significantly predicts 1-year survival. Patients transplanted with lungs from a donor with a lung donor score of 6 had a survival rate of 91%, compared to 80% and 72% for patients receiving their lungs from donors with a lung



Figure 3 Flow chart of all reported lung donors in Eurotransplant in 2008.

donor score of 7–8 points and 9 points or more, respectively (P = 0.017). (Figure 5) In a multivariate model, the effect of the lung donor score on patient mortality remained present: lung donor score of 6: hazard ratio [HR] = 1, lung donor score 7–8 HR: 2.01, 95% confidence interval [CI]: 0.88–4.59, and lung donor score 9+: HR: 3.08, CI: 1.28–7.39 (P = 0.037) (Table 4).

Discussion

Based on the six preprocurement donor factors, a donor lung score was developed that significantly predicted on an independent data set donor discard primarily due to donor-related medical reasons. In addition, the lung donor score was significantly associated with patient mortality, where patients transplanted with lung allograft from donors with a minimal score of 9 had a 1-year survival rate of 72% vs. 91% for patients transplanted with an ideal donor lung.

Experts' perceived risk

The thresholds for acceptable risk have been repeatedly reassessed. The aim of this study was not to redefine lung donor criteria, but to assess donor quality by the use of a composite score that reflects practices in lung donor acceptance built up in the last 10 years. Instead of weighing each donor factor with its associated risk of transplant failure, we opted to use a scoring system based upon actual discard rates. Hence, we standardized the experts' perceived risk of allograft failure when offered an ECD lung, and not the actual risk of graft dysfunction.

Lung donor scores

A composite donor, recipient, and intra-operative risk score was previously derived by the Toronto group to quantitate risk and allow standardized inter-center comparisons [10]. Oto et al. created a donor score that could enable a comparison between countries, allow gauging for missed donor potential, and facilitate a donor quality risk adjustment of outcome analyses [9]. As the Eurotransplant data did not contain the information needed for validating this latter score, we created and validated a new lung donor score. The selection of these donor variables (general and smoking history, age, arterial blood gases, chest X-ray, and bronchoscopic findings) was guided by these earlier studies, while the assignment of points was based on the observed associations between the different factors and discard rates in the derivation set

Clinical judgment

The procuring team plays a pivotal role in judging viability of the donor lungs. A score cannot replace this clinical judgment, and should not be used as a triage tool for sifting out unsuitable donors. As the score is based on the last preprocurement values, reaction to appropriate donor management, e.g. the time course of gas exchange, is not accounted for [11,12]. Our data showed that the lung donor score is not a perfect discriminator: donors with a low score were discarded, while others with a high score were used for transplantation. This finding is not unexpected as the score is derived from data available at the time of reporting and disregards the results of the physi-

 Table 3. Donor discard rates for the validation set: all consecutive donors reported in Eurotransplant in 2008.

			Not used donors		
Factor	Reported donors¤	Used donors‡	Donor medical reasons	Other reasons	Discard rate*
Overall	751	463	240	48	34.1%
Donor age (y)					
<45	362	240	98	24	29.0%
45–54	234	146	74	14	33.6%
55–59	91	43	43	5	50.0%
60+	64	34	25	5	42.4%
Donor history					
Compromised†	12	7	3	2	30.0%
Uncompromised	739	456	237	46	34.2%
Smoking history					
Yes	274	151	102	21	40.3%
No	352	232	99	21	29.9%
NA	125	80	39	6	32.8%
Chest X-ray					
Clear	471	332	110	29	24.9%
Edema	67	40	24	3	37.5%
Shadow	91	35	50	6	58.8%
Atelectasis	21	9	9	3	50.0%
Consolidation	39	6	30	3	83.3%
NA	62	41	17	4	29.3%
Bronchoscopy					
Clear	302	239	53	10	18.2%
Nonpurulent	42	21	16	5	43.2%
Purulent	76	24	47	5	66.2%
Inflammation	55	6	45	4	88.2%
Visualized tumor	3	0	3	0	100.0%
NA	273	173	76	24	30.5%
PO2/FiO2 (mmHg)					
>450	198	145	43	10	22.9%
351–450	215	149	55	11	27.0%
301–350	123	72	41	10	36.3%
<=300	189	82	92	15	52.9%
NA	26	15	9	2	37.5%

*Donor discard (due to donor-related medical reasons) calculation see Table 1

The donor history is compromised in case of a malignancy, sepsis, drug abuse, meningitis, or a positive virology was registered.‡At least one lung used for transplantation.

¤At least one lung reported.

cal examination of the lung at the time of retrieval and does not encompass the reassessment of subjective quality indicators such as chest X-ray.

Decreasing donor discard rates

The lung donor score can predict, using an independent data set, which donors are likely to be accepted for transplantation. This knowledge of discard rates for donors





Figure 4 Discard rate for donor-related medical reasons by lung donor score. Eurotransplant 2008. Number of donors as bars, left *Y*-axis; discard rates as line, right *Y*-axis.



Figure 5 Patient survival rates by lung donor score. All consecutive lung transplants performed in Eurotransplant in 2006. Patients transplanted with lungs from donors with 6 points: square [N = 113], with 7–8 points: circle [N = 238] and with nine or more points: triangle [N = 91].

with the same lung donor score can help in deciding whether to accept the offer, travel to the donor hospital, and judge the suitability of the organ. Our data showed that this additional step has resulted in the acceptance of lungs from donors with a compromised preprocurement donor profile.

Patient selection

This score can be used as a tool to identify extended criteria donors in a very early phase of the allocation process. There is currently a system in place at Eurotransplant that deals with allocation of some of these ECDs, by incorporating donor history in the required donor profile. The advantage of this system is that ECD lungs will only be offered to those recipients who have – at the time of listing for transplantation, and not at the

Table 4. Multivariate analysis of patient death within 1 year after transplantation. All consecutive transplants performed in Eurotransplant in 2006 (N = 442).

Factor	Ν	N HR (95% CI)	
Recipient age	442	1.003 (0.98–1.028)	0.84
Primary disease			
A	194	1	0.13
В	13	0.23 (0.03-1.80)	
С	72	0.66 (0.25-1.72)	
D	100	0.88 (0.48-1.64)	
E	63	0.28 (0.10-0.80)	
Urgency status			
HU	141	1	0.003
U	46	0.70 (0.33-1.45)	
Т	255	0.33 (0.17–0.62)	
Cold ischemia time		1.00 (0.99–1.03)	0.78
Type of transplant			
Bilateral	427	1	0.32
Single	15	1.70 (0.59–4.85)	
Number of transplant			
First	422	1	0.12
Retransplant	20	2.07 (0.83-5.18)	
Lung donor score			
6	113	1	0.037
7–8	238	2.01 (0.88-4.59)	
9 +	91	3.08 (1.28–7.39)	

A = Alpha-1 Antitrypsin Deficiency, Bronchiectasis, COPD, Emphysema, Lymphangioleiomyomatosis

B = Primary Pulmonary Hypertension, Pulmonary Vascular Disease, Eisenmenger's Syndrome, Failure of the transplant

C = Cystic Fibrosis

D = Idiopathic Pulmonary Fibrosis, Obliterative Bronchiolitis, Sarcoidosis, Other Pulmonary Fibrosis

E = Rheumatoid Disease and other

HU = high urgent, U = urgent, T = elective

time of organ offer – given their consent to accept lungs from these donors. This consent does not preclude the fact that organ offers can be discarded by the treating physician, but this system allows a directional matching procedure of ECD lungs to be achieved with the ultimate aim of reducing discard rates. Including the lung donor score into the directional matching scheme will certainly expedite the chance for acceptance of an ECD lung. Several authors already advocated the policy that ECD lungs should be reserved for a special group of patients, while ideal donor lungs would be allocated to patients with cystic fibrosis and pulmonary hypertension [13–16].

The drawback of this study is that no data on primary graft dysfunction or early lung function parameters were available. Other groups with access to these early outcome parameters should evaluate how this Eurotransplant lung donor score impacts early graft function [17]. An important limitation of our study is that our score was derived on preprocurement factors, hence any changes attributable to good donor management between reporting and procurement were not encompassed. Nor were the reassessments by the procurement team of subjective data such as chest X-ray taken into account. This might water down the effect of the score to reflect quality, but our rationale for doing so was based on the fact that the decision to accept an organ offer and actually travel to the donor center is made on data available at the time of reporting.

Eurotransplant is implementing the lung donor score as an integrated part of the donor reporting procedures. This will enable the less experienced clinicians to further judge on the suitability of a lung offer from a nonstandard risk donor. For instance, a reported lung donor with a lung donor score of 7 – hence with one factor that falls outside the acceptability criteria – had a historical discard rate of only 18%; this knowledge of peer judgment might positively influence the procurement team to travel to the donor hospital.

Optimizing lung donor recognition and maximizing lung donor usage are pivotal to increasing the number of lung transplants [18]. A validated lung donor score, based on objective preprocurement factors, can facilitate both processes. In 2008, 38% of all reported lung donors were ultimately not used for transplantation in Eurotransplant, which is excellent compared to a lung nonrecovery rate of 81% (2006 data) in the United States [19]. Eurotransplant has several mechanisms currently in place to ensure that the highest degree of effectiveness is achieved with every reported lung donor. The introduction of the lung donor score in our directional matching scheme will ensure that only eligible recipients are offered ECD lungs, thereby improving the utilization of all reported lung donors.

In conclusion, the lung donor score based on six preprocurement variables predicts the likelihood of lung donor acceptance and is associated with post-transplant outcome, and can therefore aid in donor risk assessment and patient selection.

Authorship

JMS designed research; JMS and EdV analyzed data; JMS, WvdB, and DVR wrote the paper; and JMS, WvdB, DVR, AR, GL, MdP, and BM contributed to the discussions.

Funding

The authors have declared no funding.

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