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SEQUENCE OF REFUSALS FOR DONOR QUALITY, ORGAN UTILIZATION AND SURVIVAL AFTER LUNG TRANSPLANTATION

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Abstract

Background: Lung donor utilization rates remain low with many organs refused for donor quality. However, certain centers have successfully transplanted these organs despite multiple refusals for donor quality (RDQ) by other centers. We hypothesize that the number of refusals due to donor quality does not impact post-transplant outcomes.

Methods: LTx transplants from 2006-2015 identified using the UNOS database were matched against potential transplant recipient (PTR) dataset by donor ID. Transplants were categorized into: low RDQ group (0-3 RDQ) and high RDQ group (>3 RDQ). Post-transplant survival and predictors for high RDQ were observed using Kaplan-Meier and logistic regression analysis respectively.

Results: Of 10,126 adult (>18y) LTx, 77% had at least one RDQ with a median of 4 RDQs. Post-transplant 1-year survival was similar for both low and high RDQ groups ($p=0.49$). Furthermore, groups of recipients who received donors with increasing number of RDQ (>3, >6 or >10) also had similar post-transplant 1-year survival ($p=0.77$). Treatment for rejection within 1 year and intubation at 72 hours post-transplant were higher in the high RDQ group ($p<0.01$).

There is an inverse relationship between the number of RDQ and likelihood of utilization. After 10 RDQs, likelihood of utilization varied significantly by donor characteristics.

Conclusion: Lung transplant survival is not associated with the number of refusals due to donor quality. When determining if an organ is suitable for transplant, the number of refusals due to donor quality should not influence one's decision, especially in this era of limited donor supply.

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lung transplant

INTRODUCTION

The rise in the number of lung transplants exceeds those for any organ. From 2006-2015, the number of lung transplant performed increased by 45%, with over 2000 transplants performed in 2016. The number of active and inactive waitlist additions has grown by 42% over the past decade [1]. With the growing waitlist, the waitlist list mortality has also increased from 9% in 2005 to 16% in 2015 [2]. Despite the imperative need of donor lungs, donor lung utilization remains to be strikingly low with only about 22% of donor lungs being utilized for transplant in United States and abroad [3,4,5,6].

With only about one fifth of donor lungs used for transplant, the established shortage of donor lungs may be due to an 'apparent' shortage rather than an absolute. The underutilization of donor lungs focused our research on determining the reasons for donor refusals. One of the possible causes of underutilization may be the lack of standard criteria for accepting organs. Due to variable center specific criteria, donor lungs may be refused one center that otherwise would be successfully transplanted by another. Many of these are for 'refusal due to poor quality'. However, a significant number of centers have successfully utilized donor lungs, which have been refused for poor quality in UNOS by other institutions. There may be a possibility that transplant centers use the code for donor quality as a default at times and not necessarily reflect the actual reason due to lack of specific refusal reasons in the system. The bias of seeing multiple refusals for donor quality by other centers may cause apprehension in centers evaluating that donor lung down the list.

This investigation analyzed whether donor lungs that were refused multiple times due to donor quality by other centers impacted post-transplant outcomes. We hypothesize that the number of refusals due to donor quality does not impact post-transplant outcomes. Additionally, this study examined if refusals due to donor quality impacted donor utilization. Examining the relationship between refusals due to donor quality and post-transplant outcomes has the potential to impact organ utilization.

METHODS

UNOS datasets namely the candidate, transplant, potential transplant recipient (PTR), and deceased donor dataset were used for this study. The PTR dataset contains data on all match runs for each eligible donor. For each match run, a potential recipient must accept or refuse the donor organ; if the organ is refused, a reason for refusal must be specified.

All adult (>18 yo) LTx recipients that received a lung transplant from January 1, 2006 to June 30, 2015 were identified in the transplant dataset. Due to the implementation of the lung allocation score (LAS) in 2005, recipients prior to 2006 were not examined for the transplanted recipients. LTx recipients and donor were matched against the PTR dataset and all match runs for each donor were identified. Refusals due to quality (RDQ) were

determined by selecting out the following refusal codes: 830-837,921-928,960-963 (Supplementary Table 1). Study population was divided into two groups: low RDQ group (0-3 RDQ) and high RDQ group (>3 RDQ). The cut-off point for the division of the groups was selected as such because it divided the cohort into roughly equal groups and the median is 4 RDQ. Pre-transplant recipient and donor characteristics, post-transplant events, and post-transplant survival of both cohorts were analyzed. Additionally, overall survival of low RDQ was compared to high RDQ group who received donors with >3 RDQ, >6 RDQ, and >10 RDQ. Predictors of high RDQ, predictors of recipients accepting donors with high RDQ, and overall & 1-year mortality predictors were also examined. The donor and recipient characteristics present in the mortality multivariate analysis were factors that were significant in univariate analysis.

The likelihood of utilization of a donor lung was determined by selecting potential LTx donors from 2000-2015 in the deceased donor dataset. We included the study population from 2000-2005 for this portion of the analysis in order to increase our sample size because donor factors would not be affected by the implementation of the LAS scoring system. RDQs were determined by selecting the refusal codes stated above. The cumulative likelihood of donor lung utilization is reported as a function of RDQ for different donor characteristics.

STATISTICAL ANALYSIS

IBM SPSS Statistics version 21 was used to perform statistical analysis. Summary statistics are presented as median (Interquartile range) and count (percentage). The nonparametric Mann-Whitney Wilcoxon test was used for continuous data and chi-square test for categorical data for comparing the equality of low and high RDQs for various demographic and clinical characteristics. Post-transplant survivals of recipients with various levels of RDQ were compared using nonparametric Kaplan-Meier survival curves. Multivariable analysis was performed on a set of covariates that had p-values less than or equal to 0.25 on univariate analysis, to identify recipients' potential confounders leading to accepting high RDQ donors; confounders for high RDQ donors; and for 1-year post-transplant mortality. Cox proportional hazard model, after checking the validity of the proportionality assumption, was used to determine predictors of overall post-transplant mortality. In the presentation of results, the term significant was used if the p-values < 0.05.

RESULTS

STUDY POPULATION AND REFUSALS DUE TO QUALITY

Among 10,126 adult lung transplants from January 2006 to June 2015, median recipient age was 55 yo (43-62). From the total study population, 7,837 (77.4%) recipients received a donor with one or more RDQ. The median number of RDQ per donor was 4 (1-15). From the study population, 4,928 (48.7%) recipients utilized a donor lung from the low RDQ group (0-3) and 5,198 (51.3%) utilized a donor lung from the high RDQ group (>3). The median follow-up time for all transplanted patients was 811 days (363-1643). Supplementary Figure 1 depicts the number of donor lungs at various levels of RDQ.

Out of 51,025 potential lung donors from January 2000 to June 2015, 14,942 (29.3%) lung donors were transplanted, some of which had RDQ. In remaining 36,083 unused lung donors, 10,297 (28.5%) had at least one RDQ. The remainder 25,786 lung donors were all consented donors (organ either not recovered or recovered not for transplant). There were match run on all those donors, none of which had RDQ reasons and most of them had other reasons for refusals (eg. surgeon not available or patient condition improved).

LUNG TRANSPLANT RECIPIENT CHARACTERISTICS

High RDQ group had older recipients (median: 56yo vs 55yo; $p<0.01$), more Caucasians (85.5% versus 79.4%; $p<0.01$), and more recipients with obstructive lung disease diagnosis (34.7% versus 24.9%; $p<0.01$). Low RDQ group had more race mismatch between recipient and donor (45.3% versus 40.3%; $p<0.01$), more gender mismatch between recipient and donor (33.8% versus 30.6%; $p=0.01$), had longer total days on the waitlist (74 versus 64; $p=0.005$), and higher LAS score at match (37.5 versus 35.5; $p<0.001$) (Table 1).

Multivariable analysis with the binary response variable, recipients accepting donors with low (≤ 3) or high (>3) RDQ revealed recipients who were located in UNOS region 2, diagnosed with obstructive lung diseases, were older, had a lower LAS at match, were on the waitlist for fewer days, and were non-African American were more likely to accept donors with high RDQ (>3) [Table 2].

LUNG TRANSPLANT DONOR CHARACTERISTICS

High RDQ donors were older (34yo versus 30yo; $p<0.001$), were Caucasian (64.4% versus 59.3%; $p<0.001$), were male (61% versus 56.7%; $p<0.001$), had longer ischemic times (5.78 versus 5.12; $p<0.001$), had higher incidence of clinical infection (58.9% versus 56.4%; $p=0.027$), were cigarette smokers (57.4% versus 50%; $p<0.001$), had higher incidence of CDC high risk (12.2% versus 8.4%; $p<0.001$), had more abnormal bronchoscopy findings (26.6% versus 20.1%; $p<0.001$), had more abnormal chest x-ray (52.7% versus 43.5%; $p<0.001$), and had higher incidence of $po_2: fio_2$ less than 300mmHg (9.6% versus 7.2%; $p<0.001$) [Table 3].

Multivariate analysis with the binary response variable, lung transplant donors with low (≤ 3) or high (>3) RDQ revealed that cigarette use, CDC high risk, abnormal chest x-ray, abnormal bronchoscopy findings, male, longer ischemic time, cause of death as drowning, $po_2: fio_2$ ratio less than 300mmHg, non-Hispanic, and older age in a donor are predictive factors for high RDQ (>3) [Table 4].

POST TRANSPLANT OUTCOMES

Recipients that were transplanted with donors from the high RDQ group were more likely to be intubated at 72 hours (1.6% versus 1.1%; $p=0.017$), treated for rejection within 1 year (23.4% versus 18.8%; $p<0.001$). Incidence of dialysis & stroke, hospital stay length, paO_2 , and fio_2 were not significantly different between low RDQ and high RDQ group post-transplant. There was no difference in post-transplant survival between low RDQ group and high RDQ group ($p=0.486$) [Figure 1]. Furthermore, sub-groups of recipients who received

donors with increasing number of RDQ (>3, >6 or >10) also had similar post-transplant 1-year survival ($p=0.769$) [Figure 2].

Multivariable Cox proportional hazard model for the overall mortality depicted the following as predictors as statistically significant: re-transplant recipient (hazard ratio (HR)=1.6, $p<0.001$), ventilator use at transplant (HR=1.47, $p<0.001$), cigarette user donor (HR=1.13, $p=0.015$), female recipient (HR=0.92, $p=0.019$), and group C diagnosis recipient (HR=0.87, $p=0.002$). For 1-year mortality the multivariate logistics regression model revealed the following as predictors as statistically significant: re-transplant (odds ratio (OR)=1.42, $p=0.009$), female recipient (OR=0.86, $p=0.012$), ventilator use at transplant (OR=1.76, $p<0.001$), group A diagnosis recipient (OR=0.86, $p=0.027$), group C diagnosis recipient (OR=0.7, $p<0.001$), and cigarette user donor (OR=1.24, $p=0.018$) [Table 5]. Donors with more than 3 RDQ were not significant predictors for both overall and 1-year mortality ($p=0.581$, $p=0.457$ respectively).

LIKLIHOOD OF UTILIZATION BY NUMBER OF RDQ

The likelihood of utilization varied inversely with the number of RDQs with the greatest decline occurring within the first 10 RDQs (57% likelihood at 0 RDQ vs 39% likelihood at 10 RDQ). After 10 RDQ, the likelihood of utilization is significantly lower in smokers (27.7% vs 43.5%), donors with a PaO₂:FiO₂ less than 300 mmHg (13.6% vs 53.6%), donors greater than 50 years of age (32.2% vs 42.3%), donors with evidence of clinical infection (38.7% vs 41.1%), and CDC high risk donors (34.1% vs 40.6%) [Figure 3].

DISCUSSION

Organ utilization rates remain low in lung transplants with a majority of the donor lungs never transplanted. The poor utilization rates encouraged us to further investigate the current donor acceptance practices. Our study demonstrated that refusals due to donor quality is affected by organ utilization, however it has no association with post-transplant survival. Several other key conclusions were determined in the process.

Multivariate analysis revealed the following donor factors that are associated with a high number of refusals for donor quality: cigarette use, CDC high risk, abnormal chest x-ray, abnormal bronchoscope, male, longer ischemic time (usually estimated from distance at the time of decision), cause of death as drowning, pio₂:fio₂ ratio less than 300mmHg, non-Hispanic, and older age. However, the characteristics of poor oxygenation, older donors, abnormal chest x-ray did not impact post-transplant survival in single center studies [7,8]. Additionally, the use of marginal donors (eg. >55 yo, smokers, etc) has been shown to have successful lung transplantation outcomes [9]. Using the extended criteria for donor lungs may allow more donor lungs to be utilized, thereby decreasing lung wastage [10].

Recipients more likely to accept lungs from high RDQ donors were located in UNOS region 2, diagnosed with restrictive lung diseases, were older, had a lower LAS at match, were on the waitlist for fewer days, and were non-African American. These recipients may have been on the waitlist for fewer days because their center was more likely to accept a donor with high RDQ. However, by waiting for an 'ideal donor' (eg. donor with low RDQ), the

recipient is subjected to longer wait times and possibly worse outcomes. Additionally, the association with a specific UNOS region suggests regional selection variability and center practices but was not analyzed further due to limited center or OPO level data. Interestingly, older patients and patients diagnosed with restrictive lung disease have shown to negatively impact post-transplant outcomes in previous studies [11-12]. Nonetheless, recipients who accepted high RDQ donors demonstrated no difference in survival outcomes from recipients who accepted low RDQ donors.

One of the most important findings is that it was more the recipient characteristics, rather than donor characteristics, that predicted post-lung transplant mortality [Table 5]. Similar results have been shown in previous studies [13,14-17]. Again, RDQ was shown not to predict post-transplant mortality, further strengthening the argument that RDQ is not associated with post-transplant survival. Instead of focusing on the donor characteristics when determining whether an organ is suitable for transplant, it is critical to examine recipient characteristics more than that of donors'.

Additionally, RDQ does predict donor lung utilization [Figure 3, Supplementary Table 5]. Prior refusals due to quality by other centers may be influencing centers' decisions to accept or reject the donor lung, possibly contributing to the lung wastage. Furthermore, the lung utilization is affected by donor characteristics, despite these donor characteristics having no influence on post-transplant survival. Centers may be refusing donor lungs due to RDQs by other centers, but if transplanted, the refused donor lung may have the similar survival outcomes to donor lungs that were not refused. Understanding the characteristics of non-utilized donors may assist in revising allocation algorithms to more efficiently allocate organs or consider utilization of the donor lung for other purposes such as research or Ex Vivo Lung Perfusion (EVLP).

There are several limitations to this study. When interpreting these results, it is important to consider that it remains unclear what the code 'refusal of a donor lung due to quality' represents. It may indicate that poor organ quality, injudicious use of the code as default, or a particular center's strict criteria for acceptance. Also, RDQ is likely affected by variable practices in determining donor acceptances, as well as variability in waitlist size and organ availability. Additionally, the majority of RDQ donors were not used for transplantation and it is probable that there are significant differences between the utilized and the unutilized RDQ donors. Therefore, the lack of association of post-transplant outcomes with RDQ may also reflect this selection bias, limiting the conclusions that can be drawn with reference to RDQ and outcomes. Although we assessed survival, other factors (eg. supplementary O2, exercise tolerance, and episodes of rejections) can be affected by donor quality but was not assessed due to data unavailability. Furthermore, the study is a retrospective review of a national database which allows for the potential for missing or inaccurate data. We were limited to the parameters that are entered in the UNOS database, thus other important donor and recipient factors may have been excluded.

The waitlist mortality continues to be on the rise, despite the implementation of the LAS system. Donors continue to be refused due to quality in high numbers, which influences donor utilization. However, post-transplant outcomes are not impacted by the number of

refusals due to donor quality. When confronted with a decision to accept or reject a donor, lungs should be examined in the context of their recipient, not focusing on prior refusals by centers. With the current lung shortage, the use and interpretation of donor quality refusal code should be considered carefully while selecting or refusing donors in this era of supply and demand mismatch.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1:
Kaplan Meir survival curves for post-transplant patient survival for low (≤ 3) and high (>3) RDQs

Figure 2:
Kaplan-Meier survival curves showing comparison of recipients who received donors with 0 RDQ, 1-3 RDQ, 4-6 RDQ, 7-10 RDQ, and >10 RDQ.

Figure 3:

The likelihood of donor lung utilization by donor characteristics after 10 refusals due to quality

Table 1:

Demographic and clinical characteristics of recipient at transplant reported as median (IQR) for continuous variables and frequency (%) for categorical variables for the low (≤ 3) and high (>3) RDQ groups

Characteristics	Low RDQ ≤ 3 (4928)	High RDQ >3 (5198)	P-Value *
Age (years)	55 (40-61)	56 (45-63)	<0.001
Female	2101 (42.6%)	2189 (42.1%)	0.592
Race			<0.001
White	3912 (79.4%)	4445 (85.5%)	
African American	530 (10.4%)	431 (8.3%)	
Hispanic	370 (7.4%)	223 (4.3%)	
Others	116 (2.4%)	99 (1.9%)	
Race Mismatch	2232 (45.3%)	2096 (40.3%)	<0.001
Gender Mismatch	1665 (33.8%)	1593 (30.6%)	0.001
UNOS Region			<0.001
Diagnoses			<0.001
A (obstructive lung disease)	1226 (24.6%)	1802 (34.7%)	
B (pulmonary vascular disease)	135 (2.9%)	123 (2.7%)	
C (Cystic Fibrosis)	949 (19.9%)	580 (11.7%)	
D (Restrictive lung disease)	1864 (37.9%)	1556 (29.7%)	
Other	755 (15.9%)	867 (16.7%)	
Total days on waiting list	74 (22-218)	64 (18-216)	0.005
LAS at match	37.51 (33.57-45.87)	35.73 (32.75-42)	<0.001
Blood Groups			0.144
Ventilator support at Tx	457 (9.3%)	458 (8.8%)	0.437
Eras			0.474
2006-2010	2368 (48.1%)	2535 (48.7%)	
2011-2015	2560 (51.9%)	2663 (51.1%)	

* Significant variables are mentioned in bold font, RDQ: refusal for donor quality, IQR: interquartile range, LAS: lung allocation score

Table 2:

Odds ratio estimates (95% CI) with p-values from multivariable logistic regression model with the response variable, recipients accepting donors with low (≤ 3) or high (>3) RDQ (low RDQ was a reference category)

Covariates	Odds Ratio (95% CI)	P-Value *
UNOS Region 2	2.5 (2.22-2.83)	<0.001
Diagnosis A- Obstructive Lung Disease	1.43 (1.3-1.58)	<0.001
Age (yrs)	1.01 (1.0-1.01)	<0.001
LAS at Match	0.99 (0.99-0.99)	<0.001
Waiting list >100 days	0.86 (0.79-0.99)	0.001
Black Recipient	0.69 (0.6-0.79)	<0.001
Retransplant	1.19 (0.96-1.48)	0.104
Ventilator at Transplant	0.99 (0.85-1.15)	0.909
Female Recipient	0.98 (0.9-1.07)	0.611

* Significant variables are mentioned in bold font RDQ: refusal for donor quality, IQR: interquartile range, LAS: lung allocation score

Table 3:

Lung transplant donors demographic and clinical characteristics reported as median (IQR) for continuous variables and frequency (%) for categorical variables for the low (≤ 3) and high (>3) RDQ groups

Characteristics	Low RDQ ≤ 3 (4928)	High RDQ >3 (5198)	P-Value *
Age (years)	30 (21-44)	34 (23-49)	<0.001
>50 yo	642 (13%)	1071 (20.6%)	<0.001
Female	2138 (43.3%)	2028 (39%)	<0.001
Race			<0.001
White	2922 (59.3%)	3346 (64.4%)	
Black	969 (19.7%)	939 (18.0%)	
Hispanic	840 (17.0%)	683 (13.1%)	
Others	197 (4%)	231 (4.4%)	
Ischemic Time (hrs)	5.12 (4.2-6.13)	5.78 (4.83-6.88)	<0.001
Clinical Infection	2776 (56.4%)	3061 (58.9%)	0.027
Cigarette Use	2462 (50%)	2986 (57.4%)	<0.001
CDC High Risk	414 (8.4%)	635 (12.2%)	<0.001
Abnormal Bronchoscope	990 (20.1%)	1365 (26.6%)	<0.001
Abnormal Chest X-Ray	2142 (43.5%)	2740 (52.7%)	<0.001
PaO₂:FiO₂ less than 300mmHg	357 (7.2%)	501 (9.6%)	<0.001
Pulmonary Infection	2408 (48.9%)	2635 (50.7%)	0.066
Po₂:Fio₂	449 (383-507)	439 (373-500)	<0.001

* Significant variables are mentioned in bold font, RDQ: refusal for donor quality, IQR: interquartile range, CDC: center for disease control high risk, paO₂: partial pressure of O₂, fiO₂: fractionated pressure of O₂

Table 4:

Odds ratio estimates (95% CI) with p-values from multivariable logistic regression model with the response variable, lung transplant donors with low (<3) or high (>3) RDQ (low RDQ was a reference category)

Covariates	Odds Ratio (95% CI)	P-value*
Cigarette Use	1.61 (1.4-1.87)	<0.001
CDC High Risk	1.47 (1.28-1.7)	<0.001
Abnormal Chest X-Ray	1.36 (1.25-1.48)	<0.001
Abnormal Bronchoscope	1.36 (1.23-1.51)	<0.001
Male	1.36 (1.24-1.48)	<0.001
Ischemic Time	1.31 (1.28-1.35)	<0.001
Drowning	1.26 (1.13-1.41)	<0.001
PaO₂:FiO₂ ratio <300mmHg	1.25 (1.07-1.46)	0.004
Non-Hispanic	1.24 (1.11-1.4)	<0.001
Donor Age	1.02 (1.02-1.02)	<0.001
Clinical Infection	1.07 (0.99-1.17)	0.101

* Significant variables are mentioned in bold font, RDQ: refusal for donor quality, IQR: interquartile range, CDC: center for disease control high risk, paO₂: partial pressure of O₂, fiO₂: fractionated pressure of O₂

Table 5:

Odds ratio estimates (95% CI) with p-values from multivariable logistic regression model with the response variable, 1-year mortality. Hazard ratio estimates (95% CI) with p-values from multivariable Cox proportional hazard model with the response variable, overall mortality

Covariates	Predictors of 1-year mortality		Predictors of overall Mortality	
	Odds Ratio (95% CI)	P-value *	Hazard Ratio (95% CI)	P-value *
Re-Transplant	1.42 (1.09-1.84)	0.009	1.6 (1.38-1.86)	<0.001
Ventilator at Transplant	1.76 (1.48-2.09)	<0.001	1.47 (1.32-1.63)	<0.001
Cigarette Use (donor)	1.24 (1.04-1.49)	0.018	1.13 (1.02-1.26)	0.015
Female Recipient	0.86 (0.76-0.97)	0.012	0.92 (0.86-0.99)	0.019
Group C diagnosis	0.70 (0.59-0.83)	<0.001	0.87 (0.79-0.94)	0.002
Group A diagnosis	0.86 (0.75-0.98)	0.027	0.94 (0.87-1.01)	0.107
PaO ₂ :fiO ₂ ratio <300mmHG (donor)	1.16 (0.94-1.42)	0.135	1.05 (0.93-1.18)	0.416
>3 RDQ	1.03 (0.92-1.16)	0.475	1.02 (0.95-1.09)	0.581
Abnormal Chest X-Ray (donor)	0.92 (0.82-1.03)	0.141	1.01 (0.94-1.09)	0.823
Clinical Infection (donor)	0.95 (0.85-1.07)	0.41	0.96 (0.93-1.07)	0.887
Abnormal Bronchoscope (donor)	0.97 (0.86-1.11)	0.692	0.93 (0.93-1.06)	0.843

* Significant variables are mentioned in bold font, RDQ: refusal for donor quality, IQR: interquartile range, paO₂: partial pressure of O₂, fiO₂: fractionated pressure of O₂