



Failure to rescue in the era of the lung allocation score: The impact of center volume



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ABSTRACT

Background: Failure to Rescue (FTR) is a valuable surgical quality improvement metric. The aim of this study is to assess the relationship between center volume and FTR following lung transplantation.

Methods: Using the database of the United Network for Organ Sharing (UNOS) all adult, primary, isolated lung recipients in the United States between May 2005 and March 2016 were identified. FTR was defined as operative mortality after any of five specific complications. FTR was compared across terciles of transplantation centers stratified based on operative volume.

Results: 17,185 lung recipients met study criteria. The composite FTR rate (Death following at least one complication) was 20.7%. Following stratification by volume, FTR rates increased from high to middle tercile centers (19.3% vs. 23.0%). Multivariate logistic regression models suggested an independent relationship between higher center volume and lower FTR rates ($p < 0.001$).

Conclusion: Higher volume lung transplantation centers have lower rates of failure to rescue.

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Introduction

Within the fields of cardiothoracic surgery and transplantation, post-operative complications are inevitable given the complexity of the patient population and of the procedures being performed. While short-term morbidity and mortality are widely reported measures of procedure quality, the ability to respond to and recover from complications in postoperative patients is an increasingly recognized aspect of an effective care team.¹ Failure to rescue (FTR), as defined by mortality rate associated with specific complications following surgery, has received growing attention as a new quality metric and quality improvement tool in many surgical specialties.^{2–4}

On a national level, there has been an increased focus by payers and regulators on designing initiatives to reduce postoperative complications, driven in part by wide variations in surgical mortality observed across hospitals in the United States. In 2008, the Center for Medicare and Medicaid Services (CMS) announced a

coverage policy withholding payment for preventable complications after surgery, described as “never events”.⁵ Although there is undeniable value in avoiding complications to begin with, several large independent studies have found that complication rates do not in fact differ greatly between high and low-mortality hospitals. Instead, it is a markedly reduced rate of FTR that distinguishes the best surgical centers from the worst.^{3,4}

As studies of FTR continue to populate the surgical literature, investigations into specialty and procedure specific complications will provide progressively more informative data. In cardiothoracic surgery, FTR has been described in both adult and congenital cardiac operations.^{6–10} A recent study using the Society of Thoracic Surgeons (STS) National Database found that complication rates after coronary artery bypass grafting (CABG) increased only modestly (11.4%–15.7%) between centers grouped into the lowest versus highest mortality terciles, yet FTR more than doubled (6.8%–13.9%) between these centers.⁸ Within the domain of lung transplantation (LTX), no studies to date have described national scale FTR analysis in donor organ recipients. Furthermore, while the effects of FTR are already appreciated in prior studies stratifying centers by mortality, the relationship between center volume and

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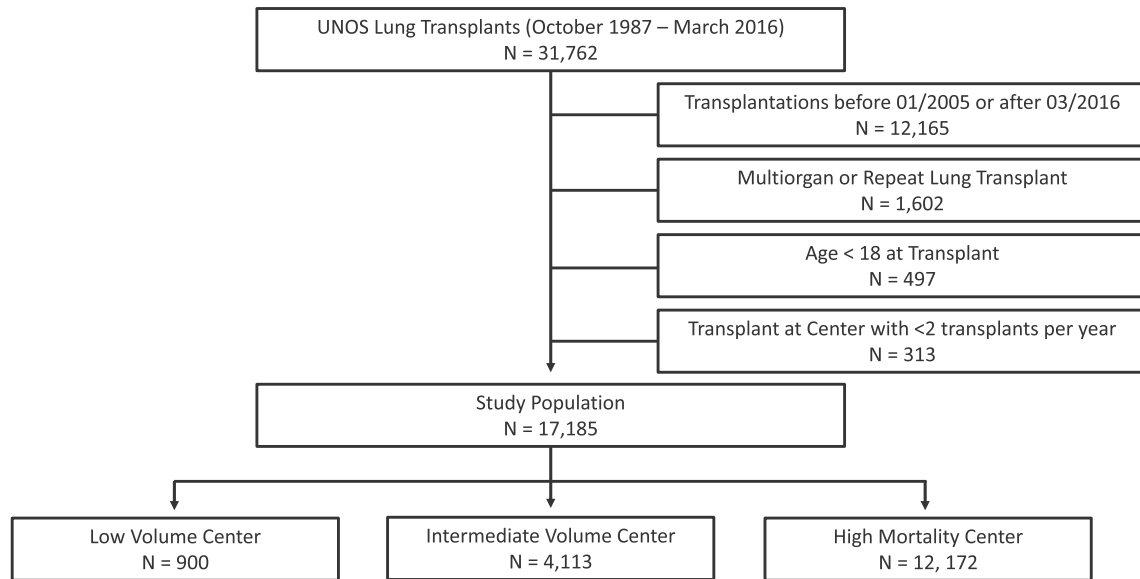


Fig. 1. Study inclusion flow diagram.

FTR is not yet well-characterized.^{8,9,11,12} Using the United Network for Organ Sharing (UNOS) national database, we sought to assess rates of FTR for postoperative complications following LTX as stratified by hospital center volume.

Materials and methods

The study was approved by the Partners Healthcare Institutional Review Board with a waiver of Informed consent.

Table 1
Donor, recipient and transplantation characteristics by center volume tercile.

	Overall	High Volume	Intermediate Volume	Low Volume	p value	Missing (n)
N (%)	17,185 (100.0%)	12,172 (70.8%)	4113 (23.9%)	900 (5.3%)		
Mortality rate, n (%)	1066 (6.2)	687 (5.6)	280 (6.8)	99 (11.0)	<0.0001	0
Donor Age, y (IQR)	32.0 (22.0–46.0)	33.0 (22.0–47.0)	30.0 (21.0–45.0)	32.0 (21.0–44.0)	<0.001	0
Female Donor, n (%)	6866 (39.9)	4953 (40.7)	1549 (37.7)	364 (40.4)	0.0027	0
Donor BMI, kg/m ² (IQR)	25.0 (22.3–28.5)	25.1 (22.3–28.6)	24.9 (22.2–28.2)	24.9 (22.4–27.8)	0.1151	13
Donor race, white, n (%)	10624 (61.8)	7514 (61.7)	2573 (62.6)	537 (59.7)	0.252	0
Donor Creatinine, mg/dl (IQR)	1.0 (0.75–1.3)	1.0 (0.7–1.3)	0.9 (0.7–1.3)	1.0 (0.8–1.4)	0.0238	22
Donor Diabetes, n (%)	1154 (6.7)	848 (6.9)	259 (6.3)	47 (5.2)	0.0581	65
Recipient age, y (IQR)	59.0 (50.0–64.0)	59.0 (50.0–65.0)	58.0 (49.0–64.0)	56.0 (41.0–62.0)	<0.001	0
Female recipient, n (%)	6981 (40.6)	4900 (40.3)	1701 (41.4)	380 (42.2)	0.2793	0
Double lung transplant, n (%)	11423 (66.5)	8304 (68.2)	2451 (59.6)	668 (74.2)	<0.0001	0
Recipient BMI, kg/m ² (IQR)	25.4 (21.5–28.7)	25.5 (21.6–28.7)	24.9 (22.2–28.2)	24.9 (20.5–28.9)	0.0034	39
Total waitlist time, d (IQR)	67 (19–209)	58.0 (16–187)	102 (30–274)	69 (26–188)	<0.0001	3
Ischemic time, h (IQR)	5.0 (3.9–6.2)	5.1 (4.1–6.3)	4.7 (3.7–5.7)	4.72 (3.5–5.9)	<0.0001	532
Etiology of Lung disease					<0.001	0
Obstructive	5071 (29.5)	3490 (28.7)	1314 (31.9)	267 (29.7)		
Restrictive	8127 (47.3)	5919 (48.6)	1855 (45.1)	353 (39.2)		
Cystic Fibrosis	2222 (12.9)	1452 (11.9)	579 (14.1)	191 (21.2)		
Primary Pulmonary HTN	631 (3.67)	488 (4.0)	127 (3.1)	16 (1.8)		
Other	1134 (6.6)	832 (6.8)	238 (5.8)	73 (8.1)		
At Transplantation						
Creatinine, mg/dl (IQR)	0.8 (0.7–1.0)	0.8 (0.7–1.0)	0.8 (0.7–1.0)	0.8 (0.7–1.0)	<0.0001	42
Hospitalized at transplant	3289 (19.2)	2311 (18.9)	808 (19.7)	169 (18.8)	0.627	1
ICU at time of transplant	1789 (10.4)	1275 (10.5)	417 (10.1)	97 (10.8)	0.7771	1
Ventilator at transplant	1214 (7.1)	974 (8.0)	187 (4.5)	53 (5.9)	<0.0001	0
Recipient race, white, n (%)	14347 (83.5)	10193 (83.7)	3446 (83.8)	708 (78.7)	0.0003	0
Diabetes, n (%)	3343 (19.6)	2354 (19.5)	808 (19.7)	181 (20.2)	0.8723	122
Independent of ADLs, n (%)	4410 (25.9)	3214 (26.7)	903 (22.4)	293 (32.)	<0.0001	198
ABO identical, n (%)	15866 (92.3)	11286 (92.7)	3793 (92.2)	787 (87.4)	<0.0001	0
HD at time of transplant, n (%)	98 (0.7)	58 (0.6)	32 (0.9)	8 (1.1)	0.0613	3139
LAS, mean (IQR)	40.5 (34.8–51.6)	40.8 (34.9–52.7)	39.8 (34.7–50.0)	39.2 (34.5–47.5)	<0.0001	9

ADLs – Activities of Daily Living, BMI – Body Mass Index, HD – Hemodialysis, HTN – Hypertension, ICU – Intensive Care Unit, IQR – Interquartile range, LAS – Lung Allocation Score.

Table 2
Recipient complication rates stratified by center volume tercile.

	High Volume	Intermediate Volume	Low Volume	p value	Missing (n)
Composite Complications, n (%)	2038 (16.7)	626 (15.2)	189 (21.0)	<0.0001	20
Dialysis, n (%)	618 (5.5)	239 (6.1)	97 (8.9)	<0.0001	75
Stroke, n (%)	231 (2.1)	69 (1.8)	39 (3.6)	0.0009	208
Acute Rejection, n (%)	989 (8.7)	321 (8.1)	103 (9.5)	0.3012	1
Airway Dehiscence, n (%)	177 (1.6)	52 (1.3)	21 (1.9)	0.3224	273
ECMO, n (%)	95 (6.2)	34 (7.1)	9 (5.2)	0.6156	14228

Others including intubation at 72 h not recorded in these patients; ECMO – Extracorporeal Membrane Oxygenation.

Study population

The study was designed as a retrospective analysis of patients who underwent lung transplantation in the United States between since the introduction of the lung allocation score (May 2005 to March 2016). Records were included in the analysis if they were primary, lung only transplantations performed in patients 18 years or older.

Data were obtained from the Scientific Registry of Transplant Recipients (SRTR) thoracic transplantation database. These data are collected by individual transplantation organizations involved in the Organ Procurement and Transplantation Network (OPTN), and supplemented by information from the Centers for Medicare and Medicaid Services (CMS) and National Technical Information Services (NTIS) Death Master File.

Characteristics and demographics

Donor characteristics available in the SRTR for study analyses included donor age, donor gender, donor body mass index (BMI), donor ethnicity, donor creatinine and donor history of diabetes.

Recipient characteristics available in the SRTR for study analyses included recipient age, recipient gender, recipient BMI, underlying diagnosis, recipient ethnicity, clinical status at the time of transplantation, recipient history of diabetes and recipient functional status at the time of transplantation. Additional transplantation factors included in the analysis included type of transplantation (single vs. double lung transplantation), number of days on the wait list, ischemic time, and ABO match for donor and recipient.

Center volume

The SRTR provides codes for each center performing lung transplantation in the United States. Each transplantation encounter is associated with a center code. Centers were stratified into Terciles (High, medium and low volume centers) based on the number of lung transplantation procedures performed per year during the study period. Centers that performed fewer than 2 transplants per year, or fewer than 10 transplants during the study period were excluded from the center volume analyses.

Table 3
Failure to rescue (FTR) rates stratified by center volume tercile.

	High Volume	Intermediate Volume	Low Volume	p value	CA Test
Composite FTR rate, n (%)	352 (19.3)	140 (22.9)	58 (25.9)	0.0197	
Dialysis, n (%)	268 (43.4)	103 (43.10)	46 (47.4)	0.7372	0.5776
ECMO at 72 h, n (%)	25 (26.3)	16 (47.1)	2 (22.1)	0.0678	0.2482
Stroke, n (%)	54 (23.4)	21 (30.4)	11 (28.2)	0.4527	0.3016
Acute Rejection, n (%)	64 (6.5)	39 (12.2)	10 (9.7)	0.004	0.0073
Airway Dehiscence, n (%)	43 (24.3)	16 (30.8)	9 (42.9)	0.1581	0.0589

CA – Cochran Armitage Trend Test, ECMO – Extracorporeal Membrane Oxygenation, FTR – Failure to Rescue.

Operative mortality and failure to rescue

An operative mortality was considered to have occurred in patients who died either within 30 days of the transplantation procedure, or prior to discharge from the original transplantation encounter.

The primary study outcome was failure to rescue (FTR) following any of five post lung transplant complications including airway dehiscence, acute kidney injury requiring hemodialysis, postoperative need for extra-corporeal membrane oxygenation (ECMO), stroke, and acute rejection. These complications were chosen based on availability of data in the UNOS database. As applied elsewhere in the literature, FTR was defined as the mortality following a given complication. It was calculated as the number of patients who suffered an operative mortality following a complication (the numerator) divided by the total number of patients who suffered that complication (the denominator). A composite failure to rescue metric was calculated as the rate of occurrence of operative mortality in patients who suffered at least one of the complications assessed in the study.

Statistical analysis

Donor, recipient and procedural characteristics were estimated for the overall population, and stratified by volume tercile. Continuous variables were described as medians and interquartile ranges, and compared across volume terciles using the analysis of variance (ANOVA) statistical model. Categorical variables were described as frequencies and percentages, and compared across center volume terciles using the Pearson chi-square statistical model. The Cochran-Armitage trend test was used to quantify the statistical significance of volume-based trends in rates of complications, operative mortality and failure to rescue.

Unadjusted logistic regression models were created to assess the effect of center volume (stratified into terciles) on occurrence of complications, operative mortality and on the composite failure to rescue metric. Multivariable logistic regression models assessed these relationships in more detail, adjusting for donor, recipient and transplantation characteristics that demonstrated statistically significant differences on univariate analysis. Hazard ratios and 95%

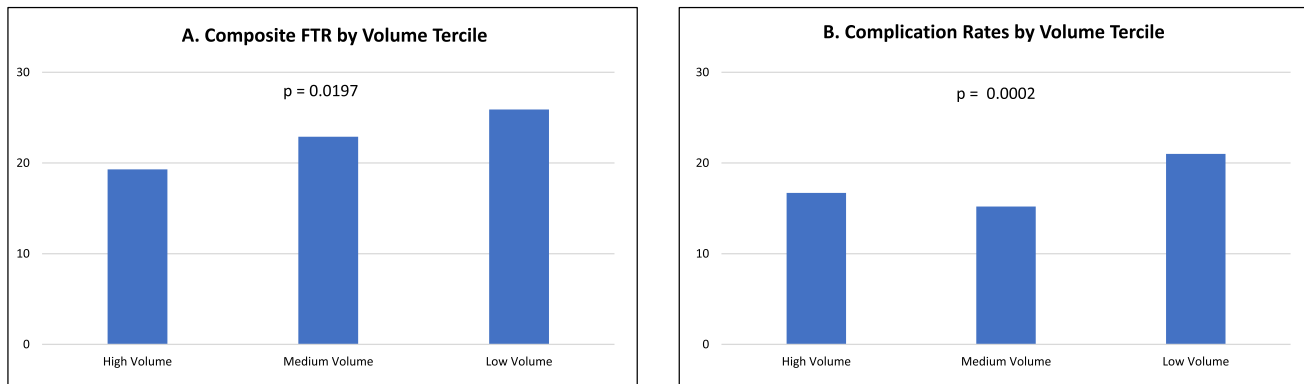


Fig. 2. Composite failure to rescue (A) and complication rates (B) stratified by volume tercile.

confidence intervals were (CIs) were computed to estimate strength and precision of associations. Unadjusted Kaplan-Meier analysis was used to demonstrate the effect of volume on long-term mortality.

Missingness in the study data was managed by excluding independent variables with greater than 20% missing data. Most variables had less than 5% of records with missing information. Analyses were performed using Student's T-tests and Pearson Chi-Square tests to compare age, gender and type of transplantation across groups of patients with missing vs. complete data. Minor differences were found, but the overall trend highlighted similarities across both groups, suggesting that missingness in the data occurred at random.

For study analyses, statistical significance was achieved with two-sided P values of 0.05 or less. Data analyses were conducted using SAS version 9.4 software (SAS Institute Inc, Cary, NC).

Results

Cohort characteristics

Query of the SRTR database generated 19,439 patients during the pre-specified study dates, 17,185 of whom remained eligible for participation following application of inclusion and exclusion criteria [Fig. 1]. The median age of transplant recipients was 59 years (IQR 50–64 years) and 40.6% of recipients were female (N = 6981). Most patients received bilateral lung transplantation (66.5%, N = 11,423) and restrictive lung disease was the most common etiology of pulmonary failure (47.3%, N = 8127). Approximately one-quarter of patients included in the study demonstrated some independence in activities of daily living at the time of transplantation (25.9%, N = 4410) [Table 1].

Characteristics stratified by center volume

Lung transplantation was performed at 76 unique centers in the United States during the study dates. 71 centers that performed at least 10 lung transplantations and maintained a rate of > two lung transplantations per year during the study dates were included in the center volume analyses. 24 centers were included in the high volume tercile and each of these centers performed at least 25 lung transplants per year. 70.8% of all lung transplantations were performed at high volume centers (N = 12,172) [Table 1]. Medium tercile centers performed at least 10.5 lung transplants per year and were responsible for ~23.9% of lung transplantation procedures (N = 4113). Lung transplantation was performed at low volume centers in only 5% of cases (N = 900).

On average, recipients at high volume centers were older (Median 59 years vs. 58 years vs. 56 years for high, medium and low terciles respectively, $p < 0.0001$), spent fewer days on the waitlist (58 days vs. 102 days vs. 69 days respectively, $p < 0.0001$), and more likely to have restrictive lung pathology as their underlying diagnosis (48.6% vs. 45.1% vs. 39.2% respectively, $p < 0.0001$) [Table 1]. There were no significant trends in donor characteristics based on center volume stratifications.

Differences in operative mortality by volume tercile were statistically significant with rates of 5.6%, 6.8% and 11.0% at high, medium and low volume centers respectively ($P < 0.0001$).

Failure to rescue: individual complications

Rate of various complications are outlined in Table 2. Acute rejection was the most common post-operative complication occurring in 8.5% of patients (N = 1413). The only complication that varied significantly in occurrence based on center volume was acute kidney injury requiring hemodialysis (5.5% vs. 6.1% vs. 8.9% at high, medium and low volume centers respectively, $p < 0.0001$).

Failure to rescue rates for individual complications are outlined in Table 3. There were no statistically significant associations between failure to rescue rates and center volume (All $P > 0.05$). There was however, a trend towards an increased rate of operative mortality for patients who suffered airway dehiscence at low volume centers (FTR rates following airway dehiscence of 24.3% vs. 30.8% vs. 42.9% at high, medium and low volume centers respectively, $p = 0.0589$) (see Table 3).

Failure to rescue: composite of all study complications

2661 lung recipients (15.5%) suffered at least one of the five study complications. Complications occurred more frequently at low volume centers compared with high and medium volume center ($p < 0.0001$) [Fig. 2].

The composite failure to rescue metric (i.e. mortality rate in patients who suffered at least one complication) was lower at high volume centers (19.3%) compared with medium (22.9%) and low volume centers (25.9%) with a statistically significant p-value = 0.019.

Regression models

Unadjusted logistic regression models with tercile of center volume as the independent variable demonstrated statistically significant differences in rates of composite failure to rescue ($p < 0.001$; HR 0.55, 95% CI 0.40–0.76), when comparing high and

Table 4
Regression models for associations between center volume tercile and failure to rescue (FTR).

Variable	Univariate			Multivariable		
	OR	95% CI	p value	OR	95% CI	p value
Volume Tercile						
High Volume	0.551	0.397–0.763	<0.001	0.466	0.323–0.674	<0.0001
Intermediate Volume	0.77	0.539–1.102	0.7641	0.617	0.414–0.920	0.4706
Low Volume	Ref	Ref	Ref	Ref	Ref	Ref
Recipient age, y	1.009	1.002–1.016	<0.0001	1.012	1.004–1.020	0.0051
Female recipient	0.735	0.610–0.886	<0.0001	0.788	0.637–0.975	0.0282
Double lung transplant	1.097	0.899–1.337	0.3626	Dropped	Dropped	NA
BMI, kg/m ²	1.011	0.992–1.030	0.2698	Dropped	Dropped	NA
Total waitlist time, d	0.999	0.9998–1.000	0.8212	Dropped	Dropped	NA
Ischemic time, h	1.028	0.978–1.079	0.2763	Dropped	Dropped	NA
Etiology of Lung disease						
Restrictive	1.063	0.889–1.272	0.5029	Dropped	Dropped	NA
At Transplantation						
Creatinine, mg/dl	1.166	1.012–1.344	0.0331	1.078	0.919–1.264	0.355
Hospitalized at transplant	1.225	1.010–1.486	0.0397	0.944	0.640–1.392	0.772
ICU at time of transplant	1.492	1.202–1.854	0.0003	1.374	0.861–2.192	0.1828
Ventilator at transplant	1.457	1.140–1.862	0.0026	1.439	0.955–2.168	0.0816
Recipient race, white	0.797	0.639–0.993	0.0428	0.787	0.613–1.011	0.0613
Recipient Diabetes	1.064	0.858–1.321	0.5715	Dropped	Dropped	NA
Recipient ADL independence	0.609	0.475–0.781	<0.0001	0.698	0.524–0.930	0.014
ABO identical	0.935	0.665–1.315	0.7006	Dropped	Dropped	NA
HD at time of transplant	2.798	1.694–4.618	<0.001	2.216	1.283–3.826	0.0043
Lung Allocation Score	1.004	1.000–1.009	0.0496	0.999	0.993–1.006	0.8443
Donor Variables						
Donor Age, y	1.003	0.997–1.010	0.289	Dropped	Dropped	NA
Female Donor	0.902	0.752–1.082	0.2656	Dropped	Dropped	NA
Donor BMI, kg/m ²	0.994	0.976–1.012	0.4886	Dropped	Dropped	NA
Donor race, white	0.801	0.667–0.961	0.017	0.755	0.615–0.928	0.0075
Donor Creatinine, mg/dl	1.019	0.959–1.082	0.5388	Dropped	Dropped	NA
Donor Diabetes	1.021	0.717–1.454	0.9091	Dropped	Dropped	NA

ADLs – Activities of Daily Living, BMI – Body Mass Index, HD – Hemodialysis, HTN – Hypertension, ICU – Intensive Care Unit.

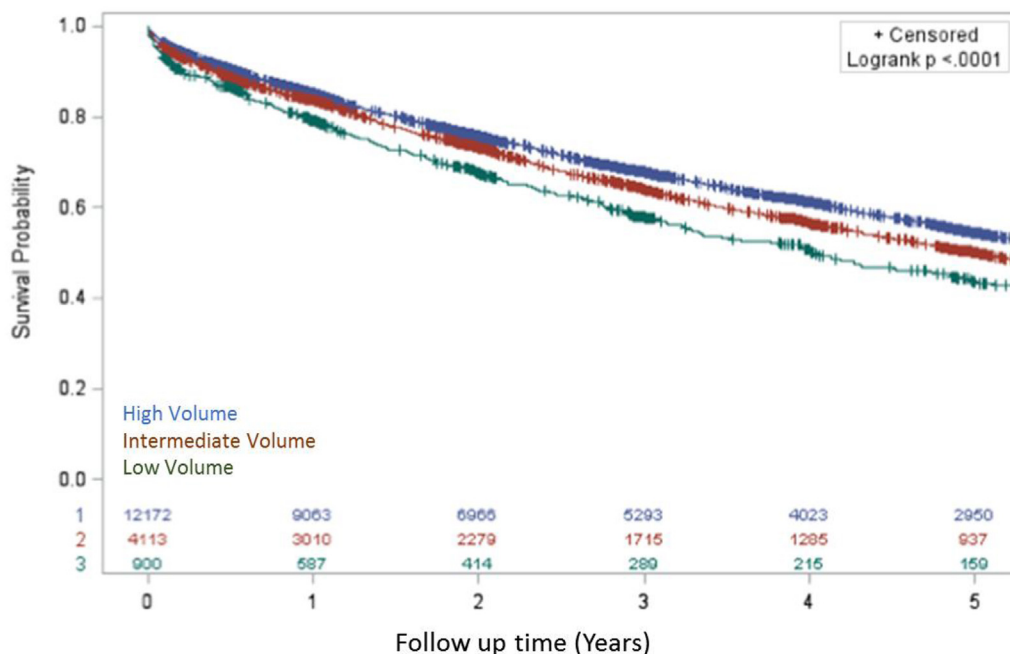


Fig. 3. Kaplan-Meier Analysis of mortality following Lung Transplantation stratified by center volume.

low volume centers (Table 4). There was a trend toward worse FTR when comparing medium to low volume centers, but this did not achieve statistical significance. Multivariate logistic regression models adjusting for age, gender, creatinine at transplant, clinical condition at transplant, functional status, donor race and lung allocation score demonstrated similar results with statistically difference in composite FTR between high and low volume centers ($p = <0.001$; HR 0.47, 95% CI 0.32–0.67) but not between medium and low volume centers ($P = 0.471$).

Unadjusted Kaplan-Meier analysis demonstrated a significant relationship between center volume and long-term mortality (Fig. 3, $p < 0.001$)

Discussion

In this analysis of adult patients undergoing lung transplantation, national rates of failure to rescue (FTR) are determined for several key post-transplant outcomes, thus establishing benchmarks that can guide monitoring and quality improvement programs at both the local and national levels. Our primary findings highlight an inverse relationship between surgical center volume and rates of post-operative complications, FTR, and early mortality, independent of both patient and transplantation factors. Differences in clinical outcomes are most pronounced between high and low volume centers, with a clear trend towards better performance at centers that fall in the high and middle tercile as compared to those that fall in the lowest tercile of surgical volume. In addition to establishing guidelines for FTR rates in lung transplantation, these findings raise important questions about what volume threshold must be maintained if a center is to perform lung transplantation safely and effectively.

Center-level differences in post-operative morbidity and mortality have been the subject of numerous articles in the surgical literature, with FTR and volume both widely accepted as consistent drivers of these outcome gaps.¹³ Previous analyses of FTR in solid organ transplantation have stratified clinical institutions by terciles of mortality, and consistently demonstrate FTR as a significant contributor to decreased survival at high mortality centers.^{14–16} Likewise, research stratifying heart and lung transplantation centers by terciles of volume have also demonstrated superior short-term, long-term, as well as waiting list survival in high-volume centers.^{15,17–22}

Although rescue and volume are both well-documented contributors to variations in surgical mortality, the association between hospital volume and FTR itself is not always clear. While FTR analyses after pancreatectomy and intracranial neoplasm resection both show increased rates of rescue at high volume centers, other national studies of patients undergoing hepatectomy and abdominal aortic aneurysm (AAA) repair fail to demonstrate any association between hospital volume and decreased FTR, and in fact indicates system level factors such as nurse-to-patient ratio as more important determinants of rescue.^{23–29}

Our findings remain consistent with existing literature demonstrating that institutional volume impacts patient outcomes after lung transplantation, and further suggests FTR to be a key driver of short-term differences between high and low volume centers.^{15,30} Recent work by Kilic et al. has reported a 9.4% improvement in 10-year survival, conditional on 1-year survival after lung transplantation in high versus low-volume centers ($p < 0.001$).²² Based on these results, their group recommended an optimal annual volume threshold of 26 lung transplants per year, which in our analysis of the UNOS database is fulfilled only by centers falling in the highest volume tercile. The appropriateness of instituting such a threshold is undoubtedly contentious, and it is important to consider that instead of representing a surgical

learning curve, operative volume is perhaps instead a surrogate marker for an institution's peri-operative resource availability. Caution, therefore, must be taken not to mistake the causes of higher volume for its effects.

The main limitations of this study are due its retrospective design and usage of the UNOS national database. Selection of complications to include in our FTR analysis was limited by the granularity of data available in the UNOS registry. It is thus possible that there are important complications left out of our analysis, yet to be identified as significant contributors to FTR variations across different lung transplantation centers. Additionally, it is unclear if increasing transplantation volume would itself improve rescue rates at higher mortality centers. It is clear however from literature in other surgical specialties that increased granularity of data is necessary to identify concrete interventions for quality improvement, such as instituting dedicated active response teams, closed ICU status, and increasing nurse-to-patient ratio.^{26,31,32} Future research in this domain will aim to explore these factors, as well as specialty specific considerations for ways to prevent FTR after lung transplantation.

Conclusion

This study highlights the significant relationship between high center volume and improved rates of rescue when patients suffer adverse events after lung transplantation. Failure to rescue thus contributes to 30-day outcome variations between high and low mortality lung transplantation centers. Failure to rescue is an important quality metric and collaboration between lung transplantation centers across the country should be encouraged to improve patient outcomes on a national level.

Declaration of competing interest

Authors have no conflicts of interest to disclose.

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