Disparities in Access to Lung Transplantation for Patients with Cystic Fibrosis by Socioeconomic Status

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Rationale: Although previous studies suggest that access to care for patients with cystic fibrosis (CF) does not vary appreciably by socioeconomic status (SES), disparities with respect to access to lung transplantation for patients with CF are largely unknown.

Objectives: To determine whether access to lung transplantation for patients with CF differs according to SES.

Methods: Observational study involving 2,167 adult patients with CF from the CF Foundation Patient registry who underwent their first lung transplant evaluation between 2001 and 2009. The primary outcome was acceptance for lung transplant after initial evaluation. The main SES indicator was Medicaid status. Alternate SES indicators included race, educational attainment, ZIP code-level median household income, and driving time from residence to closest lung transplant center.

Measurements and Main Results: The odds that Medicaid recipients were not accepted for lung transplant were 1.56-fold higher (95% confidence interval [CI], 1.27–1.92) than patients without Medicaid, after multivariate adjustment for demographic characteristics, disease severity, and potential contraindications to lung transplant, and before or after use of the lung allocation score. This association was independent of other SES indicators, including race, educational attainment, ZIP code-level median household income, and driving time to closest transplant center (odds ratio [OR] = 1.37; 95% CI, 1.10–1.72). Patients not completing high school (OR = 2.37; 95% CI, 1.49–3.79) and those residing in the lowest (vs. highest) ZIP code median household income category (OR = 1.39; 95% CI, 1.01–1.93) also experienced a higher odds of not being accepted for lung transplant in multivariate analysis.

Conclusions: In this nationally representative study of adult patients with CF, multiple indicators of low SES were associated with higher odds of not being accepted for lung transplant.

Keywords: cystic fibrosis; lung transplantation; socioeconomic status; health status disparities; health care access

AT A GLANCE COMMENTARY

Scientific Knowledge on the Subject

Previous studies suggest that access to care for patients with cystic fibrosis (CF) does not vary appreciably by socioeconomic status (SES). No previous studies have examined insurance type or other indicators of SES as determinants of access to lung transplantation in CF or any other chronic lung disease.

What This Study Adds to the Field

This study demonstrates that patients with CF of low socioeconomic position are less likely to be accepted for lung transplant. Multiple indicators of low SES, including Medicaid insurance status, belonging to the lowest median household income category by ZIP code, and not graduating from high school, were all independently associated with not being accepted. Further work is required to identify the causes of this observed disparity to improve access to lung transplantation for adult patients with CF of low socioeconomic position.

Patients with cystic fibrosis (CF) are living longer, but most will die prematurely due to progressive respiratory failure. Lung transplantation is a life-saving medical procedure that has been shown to extend survival and improve quality of life for adult patients with CF with end-stage lung disease in observational studies (1, 2). Worldwide, CF remains the third most common indication for lung transplantation and is the most common indication for bilateral lung transplantation (3).

Low socioeconomic position has been associated with worse health outcomes and increased mortality for patients with CF (4, 5). Such disparities are often attributed to barriers in accessing quality health care (6). However, previous studies suggest that access to care for patients with CF does not vary appreciably by socioeconomic status. Specifically, those of lower socioeconomic position (as indicated by eligibility for Medicaid) are just as likely to be seen in outpatient specialty clinics, receive recommended chronic therapies, and receive appropriate treatment during acute pulmonary exacerbations (5, 7, 8).

To our knowledge, no previous study has examined insurance type or other indicators of socioeconomic status (SES) as determinants of access to lung transplantation in CF or any other chronic lung disease. Data from the United States CF Foundation Patient Registry provide a unique opportunity to explore this important question. We hypothesized that low socioeconomic position would be associated with reduced access to lung transplantation.

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METHODS

Study Population and Data Sources

We used annual data from the US CF Foundation Patient Registry (CFFPR) (9) (*see online supplement*). We studied adult patients with CF 18 years of age and older with at least one annual CFFPR record between January 1, 2001 and December 31, 2009. Patients were potentially eligible for this study if they underwent their first lung transplant evaluation as an adult during this time period. A transplant evaluation indicator along with a corresponding decision of accept/decline/defer was first recorded in the CFFPR in 2000.

Socioeconomic Status Measures

We used receipt of Medicaid insurance as our primary indicator for low socioeconomic position, as this is the most common proxy for low SES in the CF literature (5, 7, 8). Medicaid status was ascertained at the time of lung transplant evaluation and was categorized as a binary variable (yes/no), independent of whether the patient had other forms of health insurance. Of the 2,187 patients referred for transplant from 2001 to 2009, 2,167 patients were eligible for analysis (Figure 1).

We also examined other potential sources of disparities, including: (1) patient-reported race, categorized as white versus nonwhite; (2) individual-level educational attainment, categorized as did not complete high school versus graduated from high school; (3) a neighborhood-level indicator of SES based on median household income of patients' residential ZIP code relative to the 2000 federal poverty level (FPL), categorized as less than 200%, 200 to 300%, or greater than 300% of FPL; and (4) quartiles of driving time from residence to closest lung transplant center (*see online supplement*).

Outcome Measure

Our outcome of interest, acceptance onto the waiting list for lung transplant after initial lung transplant evaluation, was categorized as accepted or not accepted. The not accepted group consisted of patients who were either declined or deferred. As initially deferred subjects could have been accepted on repeat evaluation, we performed a sensitivity analysis based on a final evaluation decision of accepted or declined by the end of the study period. To focus our analysis on those individuals most likely to be considered for lung transplant, we also conducted a sensitivity analysis restricting to patients with an FEV₁ of less than 30% and without potential contraindications.

Statistical Analyses

Descriptive statistics were produced for and compared between Medicaid versus non-Medicaid patients at the time of lung transplant

evaluation. Continuous variables were evaluated with Student's *t* test and categorical variables with Fisher's exact test. Unless otherwise specified, covariate values were ascertained in the same year as initial transplant evaluation.

Bivariate associations between each covariate and the binary outcome of accepted or not accepted were examined using logistic regression. We then fit a series of multivariate logistic regression models to examine the association between Medicaid status as the primary SES indicator and the binary outcome of accepted or not accepted for lung transplant to assess the impact of various potential confounders on our risk estimates (*see online supplement*). With an estimated sample size of 2000 patients undergoing lung transplant evaluation from 2001 to 2009, we had 90% power to detect an odds ratio (OR) of 1.25 or greater for the association between Medicaid status and not being accepted for lung transplant. The above approach to multivariate model building was then repeated, replacing the primary predictor, Medicaid status, with each of the other four SES indicators: race, educational attainment, ZIP code-level median household income, and driving time from residence to closest lung transplant center. Statistical significance was set at *P* less than 0.05, and all statistical tests were two-sided. Analyses were performed using STATA 12.0 (StataCorp).

RESULTS

Cohort Characteristics

Of the 2,167 patients included in this study, 1,009 (47%) were Medicaid recipients and 1,158 (53%) did not receive Medicaid. At the time of lung transplant evaluation, patients with Medicaid were significantly younger and more likely to be nonwhite (Table 1). Despite their younger age, Medicaid recipients had more severe disease as reflected by a greater number of acute exacerbations in the previous year, greater requirement for supplemental oxygen and noninvasive mechanical ventilation, lower body mass index, and a higher prevalence of CF-related diabetes requiring insulin. Medicaid recipients were also less likely to have a partner as social support. Receipt of Medicaid was associated with other indicators of low socioeconomic position, including lack of high school completion, residence in the farthest quartile in terms of driving time from the closest lung transplant center, and belonging to the lowest ZIP code-level median household income category.

Bivariate Analysis

The following SES indicators were significantly associated with not being accepted for lung transplant: Medicaid insurance

Figure 1. Study cohort selection of adult patients with cystic fibrosis undergoing their first lung transplant evaluation, 2001 to 2009. LTx = lung transplant.

TABLE 1. SOCIODEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF ADULT PATIENTS WITH CYSTIC FIBROSIS (≥18 YR) UNDERGOING INITIAL LUNG TRANSPLANT EVALUATION, 2001–2009

	Any Medicaid (n = 1,009)	No Medicaid (n = 1,158)	P Value*
Other SES Indicators			
Nonwhite race	91 (9)	51 (4)	<0.001
Did not complete high school	94 (10)	27 (3)	<0.001
Quartile of driving time from residence to closest LTx center			<0.001
0–25% (<30 min)	204 (21)	343 (30)	
25–50% (30–75 min)	246 (25)	290 (26)	
50–75% (75–150 min)	259 (26)	251 (22)	
75–100% (>150 min)	271 (28)	245 (22)	
Median household income by residence ZIP code relative to FPL			<0.001
>300%	208 (22)	416 (38)	
200–300%	472 (49)	495 (45)	
<200%	283 (29)	190 (17)	
Demographic characteristics			
Age, mean (SD), yr	28 (8)	32 (10)	<0.001
Male sex	495 (49)	596 (51)	0.26
Indicators of disease severity			
FEV ₁ % predicted, mean (SD)	31 (12)	32 (14)	0.13
No. of acute exacerbations in past year, mean (SD)	3.5 (2.7)	2.7 (2.4)	<0.001
Supplemental oxygen use	744 (75)	796 (70)	0.01
Noninvasive mechanical ventilation use	146 (15)	120 (10)	0.004
Body mass index in kg/m ² , mean (SD)	19.4 (3.0)	19.9 (3.1)	<0.001
CFRD on insulin	410 (41)	387 (33)	<0.001
Potential contraindications to LTx			
<i>Burkholderia cepacia</i> culture positive	57 (6)	79 (7)	0.25
Nontuberculous mycobacteria culture positive	23 (2)	40 (4)	0.12
Cirrhosis with portal hypertension	35 (4)	48 (4)	0.44
Renal failure requiring dialysis	15 (1.5)	13 (1.1)	0.45
Osteoporosis	145 (15)	140 (12)	0.11
Cancer	6 (0.6)	7 (0.6)	1.00
Smoking	8 (0.8)	2 (0.2)	0.05
Depression	295 (30)	261 (23)	<0.001
No partner	708 (72)	572 (50)	<0.001
<4 Outpatient visits in past yr	192 (19)	234 (20)	0.52
LTx period			
Evaluated since use of lung allocation score (2005+)	553 (55)	631 (54)	0.90

Definition of abbreviations: CFRD = cystic fibrosis–related diabetes; FPL = federal poverty level; LTx = lung transplant; SES = socioeconomic status.

Data are presented as n (%) unless otherwise noted.

* Student's *t* test or Fisher's exact test.

status, nonwhite race, not completing high school, and living within a lower median household income category by ZIP code relative to the highest (all $P < 0.05$) (see Figure E1 in the online supplement). Individuals with the following characteristics were also less likely to be accepted for lung transplant: underweight, with a body mass index of less than 18 kg/m²; cirrhosis complicated by portal hypertension; active smoking history; without a spouse/partner as a form of social support; nonadherent with recommended outpatient follow-up visits to a CF clinic; and evaluation for transplant since introduction of the lung allocation score (all $P < 0.05$). Supplemental oxygen use was associated with being more likely to be accepted for lung transplant ($P = 0.01$).

Multivariable Analysis

Primary SES indicator: Medicaid status. After adjustment for age and sex (Model 1), the odds of not being accepted for lung transplant after initial evaluation were 1.51-fold higher (95% confidence interval [CI], 1.25–1.82) for Medicaid recipients compared with patients without Medicaid (Table 2). The OR of Model 1 did not change materially after adjustment for underlying differences between Medicaid and non-Medicaid patients with respect to disease severity (Model 2: adjusted OR [aOR], 1.55; 95% CI, 1.27–1.89), potential contraindications to lung transplant (Model 3: aOR, 1.55; 95% CI, 1.26–1.90),

before versus after use of the lung allocation score (LAS) (Model 4: aOR, 1.56; 95% CI, 1.27–1.92), and other SES indicators (Model 5: aOR, 1.37; 95% CI, 1.10–1.72).

Tests for interaction did not provide evidence that introduction of the LAS significantly modified the relation between Medicaid status and not being accepted for lung transplant ($P = 0.39$). In a sensitivity analysis comparing patients who were ultimately accepted to those who were ultimately declined by the end of cohort follow-up, the effect sizes for the association between SES indicators and being declined for lung transplant were larger than the primary analysis (Table E1). Furthermore, a sensitivity analysis restricting the analysis to patients with an FEV₁ of less than 30% predicted and without contraindications did not meaningfully change the results (Table E2).

Additional SES indicators. After adjustment for potential mediators and/or confounders (Model 4), individuals who were nonwhite (aOR, 1.51; 95% CI, 1.08–2.12), did not complete high school (aOR, 2.74; 95% CI, 1.73–4.34), and resided within a neighborhood with a ZIP code median household income of less than 200% of the FPL (vs. >300% of the FPL) (aOR, 1.72; 95% CI, 1.29–2.28) were associated with not being accepted for lung transplant (Table 2). After additional adjustment for the other SES indicators (Model 5), only individuals who did not complete high school (aOR, 2.37; 95% CI, 1.49–3.79) or who resided within a ZIP code with a median household income of

TABLE 2. MULTIVARIABLE LOGISTIC REGRESSION MODELS EVALUATING THE ODDS OF NOT BEING ACCEPTED FOR LUNG TRANSPLANT AFTER INITIAL EVALUATION IN ADULT PATIENTS WITH CYSTIC FIBROSIS FROM 2001 TO 2009 FOR EACH SOCIOECONOMIC STATUS INDICATOR

Primary SES Indicator	n	%	Model 1: Base Model Adjusted for Age and Sex		Model 2: Model 1 + Indicators of Disease Severity*		Model 3: Model 2 + Potential LTx Contraindications†		Model 4: Model 3 + Before vs. After Use of LAS		Model 5: Model 4 + Other SES Indicators	
			OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI
Medicaid recipient												
No	1,158	53	1	REF	1	REF	1	REF	1	REF	1	REF
Yes	1,009	47	1.51	1.25–1.82	1.55	1.27–1.89	1.55	1.26–1.90	1.56	1.27–1.92	1.37	1.10–1.72
Race												
White	2,021	93	1	REF	1	REF	1	REF	1	REF	1	REF
Nonwhite	142	7	1.56	1.14–2.14	1.62	1.15–2.27	1.50	1.08–2.10	1.51	1.08–2.12	1.23	0.78–1.93
Completed high school												
Yes	1,837	94	1	REF	1	REF	1	REF	1	REF	1	REF
No	121	6	2.68	1.84–3.91	2.84	1.87–4.30	2.72	1.72–4.29	2.74	1.73–4.34	2.37	1.49–3.79
Median household income by residence ZIP code relative to FPL												
>300%	624	30	1	REF	1	REF	1	REF	1	REF	1	REF
200–300%	967	47	1.13	0.95–1.34	1.17	0.96–1.42	1.21	0.97–1.50	1.21	0.98–1.50	1.11	0.89–1.38
<200%	473	23	1.42	1.11–1.83	1.56	1.18–2.07	1.68	1.26–2.24	1.72	1.29–2.28	1.39	1.01–1.93
Driving time from residence to closest LTx center, min												
<30	547	26	1	REF	1	REF	1	REF	1	REF	1	REF
30–75	536	25	1.19	0.89–1.58	1.17	0.88–1.54	1.17	0.87–1.55	1.13	0.85–1.51	1.08	0.81–1.42
75–150	510	24	1.26	0.96–1.66	1.21	0.90–1.63	1.20	0.89–1.62	1.18	0.87–1.60	1.05	0.76–1.45
>150	516	24	1.39	1.05–1.83	1.38	1.01–1.87	1.36	0.99–1.89	1.33	0.96–1.84	1.18	0.83–1.67

Definition of abbreviations: FPL = federal poverty level; LAS = lung allocation score; LTx = lung transplant; REF = reference group; SES = socioeconomic status.

Robust estimates of variance with transplant center as the cluster (grouping) variable.

* Indicators of disease severity: FEV₁ % predicted, number of acute exacerbations per year, supplemental oxygen use, noninvasive mechanical ventilation use, body mass index, cystic fibrosis–related diabetes.

† Potential LTx contraindications: *Burkholderia cepacia* culture positive, nontuberculous mycobacteria positive, cirrhosis with portal hypertension, renal failure requiring dialysis, osteoporosis, cancer, smoker, no partner, nonadherent with outpatient visits.

less than 200% of the FPL (vs. >300% of the FPL) (aOR, 1.39; 95% CI, 1.01–1.93) were independently associated with not being accepted for lung transplant.

DISCUSSION

We found that the odds of not being accepted for lung transplant were 1.56-fold higher for Medicaid compared with non-Medicaid patients. This key finding was independent of differences in demographic factors, disease severity indicators, potential contraindications to lung transplant, and before or after use of the LAS between Medicaid and non-Medicaid patients. To our knowledge, this is the first study to examine disparities with respect to access to lung transplant early in the evaluation process (i.e., before lung transplant wait listing). Although the United Network of Organ Sharing (UNOS) oversees organ allocation in the United States and has a mandate to ensure access will not be based on “political influence, race, gender, religion, or financial or social status,” this governance is primarily limited to after wait listing (10). Our study also demonstrates that other indices of low SES, including not graduating from high school and residing in lower-income ZIP codes, were independently associated with not being accepted after lung transplant evaluation.

The underlying reasons for disparities in access to lung transplant for patients with CF of low SES are likely complex and multifactorial. Inadequate social support and noncompliance with medical regimens represent two key contraindications to lung transplant candidacy. Although we used the best available proxies to adjust for these important mediators in our analysis, these two factors are difficult to measure comprehensively based on data available in the CFFPR. Therefore, Medicaid and our other indicators of low SES might cluster with these incompletely measured factors. Not graduating from high school was the SES indicator most strongly associated with not being accepted for transplant, suggesting that educational attainment may

influence acceptance beyond its role as an SES indicator. Transplant physicians might be less willing to wait-list patients with inadequate health literacy due to concerns about post-transplant compliance with treatment regimens, as has been suggested to be the case in the renal transplant literature (11). Although we have implied that disparities in access to transplant are largely physician driven, it is possible that the apparent disparity is due to patient choice. For example, individuals of low SES might prefer not to be transplanted due to lack of perceived benefit. Patients living farther away from a lung transplant center tended to be of lower SES, and therefore geographical barriers might have influenced their decision not to proceed with transplant. Interestingly, driving time from residence to closest lung transplant center (by quartile) was not independently associated with not being accepted for lung transplant when adjusted for other SES indicators. This lack of association supports a previous finding from the renal transplant literature, which failed to demonstrate reduced access to kidney transplant for patients residing farther from the nearest transplant center (12).

Another major observation from our study is that Medicaid patients were younger and sicker than their non-Medicaid counterparts at the time of initial lung transplant evaluation. First, this suggests that Medicaid patients are referred later than non-Medicaid patients, as they are sicker at the time of evaluation. Second, this suggests that nutrition, medical management (including adherence to therapies), and/or access to care might be worse for patients of low socioeconomic position, as they are younger at the time of needing a transplant. This is consistent with previous studies that have demonstrated differences with respect to health outcomes by SES. However, this observation needs to be interpreted with some caution, as sicker patients might be more likely to qualify for Medicaid, thus leading to reverse causation.

Our study is subject to a few important limitations. First, we used Medicaid as a proxy for low socioeconomic position. This proxy has been criticized in previous studies (8); patients with more severe disease are more likely to qualify for Medicaid, as medical expenses are considered when evaluating eligibility (13). Although this can be problematic when studying the association between SES and health outcomes, this may not be a significant limitation when studying access to care, particularly when disease severity is accounted for. As there is no single accepted measure for SES (14), we examined four alternate indicators of low socioeconomic position, each of which has inherent limitations. Median household income by ZIP code is an ecologic measure and therefore requires relative homogeneity of household income within a geographic region for it to be a reliable measure of individual-level SES in nonlinear models (15). Therefore, these results should not be interpreted at the individual level; rather, these results should be seen as an area level effect that could represent a larger, multifactorial effect resulting in less access to care. Estimation of distance from residence to closest lung transplant center was also an ecologic measure that required a few assumptions. We assumed that patients chose their transplant center based on proximity alone (e.g., patients did not travel longer to another center of choice) without respect to interstate boundaries and that comorbidities (e.g., colonization with *Burkholderia cepacia*) did not influence selection of transplant center. We chose driving time as opposed to road distance, as travel times for identical road distance can vary based on highway versus city versus rural driving. High school graduation also has limitations, as graduation may be affected by disease severity, with more severely diseased patients missing more schooling due to illness.

Our analysis focused on the decision of the initial lung transplant evaluation. A potential concern is that approximately one-third of patients were deferred and thus classified as not accepted. We chose to classify patients initially deferred as not accepted, as initial deferral might have similar implications to being rejected. For example, deferral may lead to critical delays, such that these patients might be more likely to die before wait listing, thus reducing their opportunity for transplant. To support this reasoning and classification, 167 of 370 patients (45%) initially deferred died while still being classified as deferred. Nevertheless, patients initially deferred could have been accepted during repeat evaluation, especially if they were referred too early, required further work-up, and/or needed time for medical optimization. To evaluate the effect of this potential misclassification, we performed a sensitivity analysis comparing patients who were ultimately accepted to those who were ultimately declined for transplant at the end of cohort follow-up. This resulted in a slightly stronger association between low socioeconomic position and reduced access to transplant. Furthermore, we conducted a sensitivity analysis restricting to patients with a FEV₁ of less than 30% and without potential contraindications in an attempt to focus our analysis on those individuals most likely to be considered for transplantation and had results similar to our primary analysis.

An additional limitation is that we presented our analysis using ORs and not risk ratios. ORs tend to overestimate effect sizes for nonrare outcomes, thus limiting the interpretation of absolute values. However, our study was designed to explore potential associations between SES indicators and access to transplant rather than to highlight or compare the absolute strengths of any associations.

Our study findings are concerning, since virtually all patients with end-stage CF have health insurance and are followed at an accredited CF care center. Despite this, there was still a strong differential access to lung transplant by SES. The differences

observed in CF are likely exaggerated in other pre-lung transplant populations, such as chronic obstructive pulmonary disease and idiopathic pulmonary fibrosis, whereby a wider spectrum exists with respect to quality of care and health insurance coverage. It remains unclear as to why patients with CF of low socioeconomic position experience differential access to lung transplant, but it does not appear to be related to underlying differences in disease severity or potential contraindications. It is possible that residual confounding and/or mediation were introduced. For example, patient frailty and poor functional status are not measured in the CFFPR but may represent reasons that patients of low socioeconomic position have higher odds of not being accepted for transplant. Furthermore, we were unable to account for social habits such as alcohol or other substance abuse that are likely more common among patients of low SES and may also represent contraindications to lung transplant. We believe the overall influence of residual confounding/mediation on our results is likely minimal, as we have adjusted for a number of variables with little or no impact on the strength of the association between Medicaid insurance and not being accepted for lung transplant.

In conclusion, we found evidence that acceptance for lung transplantation was lower for patients with CF of low socioeconomic position. We in the medical community need to support an urgent call for studies and evaluations to (1) explore factors associated with Medicaid status that preclude lung transplant listing to improve access to lung transplantation for adult patients with CF of low socioeconomic position, and (2) investigate whether this differential access to care is present in other populations in which evaluation for lung transplant occurs.

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