

Trends in Survival for Adult Organ Transplantation

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Objective: Intent-to-treat analysis follows patients from listing to death, regardless of their transplant status, and aims to provide a more holistic scope of the progress made in adult solid-organ transplantation.

Background: Many studies have shown progress in waitlist and post-transplant survival for adult kidney, liver, heart, and lung transplants, but there is a need to provide a more comprehensive perspective of transplant outcomes for patients and their families.

Methods: Univariable and multivariable Cox regression analyses were used to analyze factors contributing to intent-to-treat survival in 813,862 adults listed for kidney, liver, heart, and lung transplants. The Kaplan–Meier method was used to examine changes in waitlist, post-transplant, and intent-to-treat survival. Transplantation rates were compared using χ^2 tests.

Results: Intent-to-treat survival has steadily increased for liver, heart, and lung transplants. The percentage of patients transplanted within 1 year significantly increased for heart (57.4% from 52.9%) and lung (73.5% from 33.2%). However, the percentage of patients transplanted within 1 year significantly decreased from 35.8% to 21.2% for kidney transplant. Notably, intent-to-treat survival has decreased for kidneys despite increases in waitlist and post-transplant survival, likely because of the decreased transplant rate.

Conclusion: Intent-to-treat survival steadily improved for liver, heart, and lung transplant over the 30-year study period. Continued advancements in allocation policy, immunosuppression, and improved care of patients on the waitlist may contribute to further progress in outcomes of all organs, but the increasing discrepancy in supply and demand of donor kidneys is alarming and has impeded the progress of kidney intent-to-treat survival.

Keywords: heart, intent-to-treat, kidney, liver, lung, organ transplant, outcomes, post-transplant, solid organ, survival, transplantation, transplant, waitlist

INTRODUCTION

The field of solid-organ transplantation has greatly evolved over the last 3 decades with changes in organ allocation, allograft usage, and immunosuppression.¹ Such changes were made to improve and optimize the survival of patients before and after transplantation. Waitlist and post-transplant survival are important to consider when evaluating transplantation

outcomes in relation to patient priorities, as some patients prioritize waitlist outcomes while others prioritize post-transplant outcomes.^{2,3} Furthermore, from the patient's perspective, the experienced outcome is a combination of waitlist and post-transplant outcomes.

Both waitlist survival and post-transplant survival have shown steady improvements for kidney transplant, largely due to better maintenance of dialysis and diabetes care.^{4–8} In the population of patients listed for liver transplantation, waitlist mortality has improved, likely due to aggressive use of marginal allografts and the “Share 35” policy.^{9,10} The Organ Procurement and Transplantation Network (OPTN) liver data report also suggests improvements in post-transplant patient survival during recent years.¹¹ Patients on the heart transplant waiting list have shown improvements over 30 years, likely due to optimized listing behaviors, medical management, and improved mechanical devices.¹² Despite an increase in the proportion of older heart transplant recipients, post-transplant survival has also improved over the last 3 decades.^{13,14} For lung transplantation, waitlist survival has decreased slightly over the years.¹⁵ However, post-transplant survival has shown improvement over the last 3 decades, with a median survival of 6.7 years in the 2010–2017 era. Improvements have been attributed to increased transplant volume, changes in donor selection and organ preservation, and improved medical management.¹⁶

Organ shortage has become one of the primary reasons why waitlist survival and post-transplant survival must be both carefully and collectively considered for solid-organ transplant candidates, as not every patient who is listed is able to receive a transplant.¹⁷ More importantly, it is imperative to evaluate the progress that has been made, or that remains to be made, in the different organs from a perspective that considers both waitlist survival and post-transplant survival together. An intent-to-treat (ITT) analysis is patient-centric and allows for survival analysis from the time of waitlist inclusion rather than from the time of transplant, thereby analyzing outcomes based on initial treatment assignment instead of treatment eventually received.^{18,19} Therefore, the ITT perspective provides a more comprehensive

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All data was obtained from de-identified patients in the OPTN database.

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outlook for patients that is applicable on the day of listing. An ITT analysis allows us to better distinguish between the need to transplant as many patients as possible and the need to primarily select patients who are most likely to benefit from transplantation.²⁰ The purpose of our analysis is to examine changes in ITT outcomes in adult kidney, liver, heart, and lung transplantation from 1990 to 2019. This approach will contribute to a more patient-centered understanding of the progress made in adult solid-organ transplantation. This can have a greater impact on patient engagement, the balance between functional efficacy of the graft and patient well-being, optimization of follow-up care, and overall quality of life.²¹

METHODS

Study Population

A retrospective analysis was performed on patient-level data from the OPTN, including patients aged 18 and older listed for kidney (n = 483,523), liver (n = 202,096), heart (n = 79,563), and lung (n = 48,680) transplant between January 1, 1990 and December 31, 2019. Only patient characteristics reported at the time of listing were used in this analysis. Institutional review board approval was waived due to the use of de-identified publicly available data.

Patients listed for multiple organs (n = 69,435 [kidney, 44,581; liver, 16,871; heart, 5,862; and lung, 2,121]), those who had a history of previous transplant (n = 46,011 [kidney, 41,361; liver, 3,052; heart, 1,156; and lung, 442]), and those who had multiple entries in the OPTN database (n = 99,923 [kidney, 77,019; liver, 15,936; heart, 4,017; and lung, 2,951]) were excluded from this study. Patients with multiple entries in the OPTN database included those who were made inactive or de-listed at one center and re-listed at another during their waiting period. These patients were excluded for simplicity and to avoid individual patients being counted as multiple observations in ITT survival analysis.

Data analysis was performed using Stata 16.1 (Stata Corp, College Station, TX), a standard statistical software. Continuous variables were reported as mean ± standard deviation and compared using the Student's *t*-test. Categorical variables were reported as percentages and were compared using the chi-squared test. Results are considered significant at a *P* value <0.05. All reported *p*-values are two-sided.

Intent-to-Treat Survival

For analysis of ITT survival, univariable and multivariable Cox regression was used in addition to the Kaplan–Meier method with the log-rank test. The primary outcome measured was patient death following listing for transplantation, either on the waitlist or post-transplant. Removal from the waitlist due to clinical deterioration deemed unsuitable for transplant was considered equivalent to death in this analysis.

Variable inclusion in univariable Cox regression varied by organ and was restricted to entry completion in the OPTN database above 90%. For all organs, patient age, height, weight, sex, and body mass index were included. Dependence on life support (e.g., ventilator, extracorporeal membrane oxygenation, ventricular assist device, etc.) was included as a variable for analysis of liver, heart, and lung transplant. Designation as status 1 was used as a variable for the analysis of liver and heart transplant. For kidney transplant, other variables included diagnosis of diabetes, hypertensive nephropathy, polycystic kidney disease, and donor type. For liver transplant, other variables included prior abdominal surgery, spontaneous bacterial peritonitis, portal vein thrombosis, transjugular intrahepatic portosystemic shunt, diagnosis of hepatitis C, alcoholic cirrhosis, and nonalcoholic steatohepatitis. For heart transplant, other variables included prior

cardiac surgery, diagnosis of idiopathic dilated cardiomyopathy, ischemic cardiomyopathy, and coronary artery disease. For lung transplant, other variables included classification within disease group A (obstructive lung disease), disease group B (pulmonary vascular disease), disease group C (cystic fibrosis or immunodeficiency disorder), and disease group D (restrictive lung disease). Variables significant in univariable regression (*P* < 0.05) were included in multivariable regression in addition to the decade of listing (1990–1999, 2000–2009, 2010–2019). In both Cox regression and Kaplan–Meier survival analysis, the 2010–2019 decade was used as a reference to which the previous 2 decades were compared. We ran a supplemental Kaplan–Meier survival analysis analyzing ITT survival before and after some of the major changes in organ allocation, including the new kidney allocation system, broader sharing policies, the introductions of the 3-tiered classification for heart transplant, model for end-stage liver disease (MELD) scores and hepatocellular carcinoma points, and the new Lung Allocation System (LAS).

Waitlist and Post-transplant Survival

The Kaplan–Meier method with the log-rank test was also used for the analysis of waitlist and post-transplant survival. Like the analysis of ITT survival, the 2010–2019 decade was used as a reference to which survival in the previous 2 decades was compared. For waitlist survival analysis, the primary outcome measured was death on the waitlist or removal due to clinical deterioration deemed unsuitable for transplant. Patients were followed from listing until death, removal, or transplantation.

For post-transplant survival analysis, the primary outcome measured was death following a transplant procedure. Only patients who received a transplant were included (n = 479,146 [kidney, 268,606; liver, 120,096; heart, 54,930; and lung, 35,514]), and time on the waitlist had no bearing on this portion of the analysis. Patients were followed from transplantation until death or last known follow-up.

Percent Transplanted

For all organs, the chi-squared test was used to compare the percentage of patients who received a transplant within 3 months, 6 months, and 1 year of listing. Patients who were listed less than the period of interest before the end of the study period were not included in this portion of the analysis to prevent bias against the most recent decade. The 2010–2019 decade was used as a reference to which transplantation rates in previous decades were compared.

RESULTS

Study Population

The study population was composed of 813,862 first-time transplant candidates on the waitlist between 1990 and 2019. Of these, 483,523 candidates were listed for kidney, 264,550 candidates were listed for liver, 79,563 candidates were listed for heart, and 48,680 candidates were listed for lung. Demographics of the transplant candidates across the 3 decades can be seen in supplemental material (Supplemental Table 1, <http://links.lww.com/AOSO/A291>).

Univariable and Multivariable Intent-to-Treat Analysis

Univariable and multivariable analysis using Cox regression was utilized for each organ to analyze the effects of risk factors on ITT survival, measuring survival from listing to death irrespective of the candidate receiving a transplant. If risk factors in univariable analysis were statistically significant (*P* < 0.05) (Supplemental Table 2, <http://links.lww.com/AOSO/A292>, which shows results of univariable analysis), the factors

were included in multivariable analysis. The results of the multivariable analysis can be seen in the supplemental material (Supplemental Table 3, <http://links.lww.com/AOSO/A293>). Statistically significant factors ($P < 0.05$) were considered significant predictors for the outcome—death following listing for transplant after receiving a transplant, or on the waitlist. Additionally, Multivariable analysis also includes the decade of listing (1990–1999, 2000–2009, and 2010–2019). Using the recent decade (2010–2019) as a reference, multivariable analysis shows that listing decade is a statistically significant predictor in ITT analysis. The previous 2 decades (1990–1999 and 2000–2009) show increased risk for all organs. Additionally, the first decade (1990–1999) had a higher risk than the second decade (2000–2009) for all organs.

Kaplan–Meier and Log-Rank Analysis

Kaplan–Meier survival analysis was utilized to determine the effect of each decade on waitlist, post-transplant, and ITT survival. Figure 1 shows the ITT Kaplan–Meier curves for the four organs. The subsequent log-rank tests were used to determine statistical differences between decades. Waitlist and post-transplant Kaplan–Meier curves can be found in the supplemental digital content (Supplemental Figures 4–5, <http://links.lww.com/AOSO/A294>).

For kidney, waitlist and post-transplant survival of patients listed from 1990–1999 to 2000–2009 were reduced and statistically different ($P < 0.05$) compared to 2010–2019. ITT survival from 1990–1999 to 2000–2009 was superior when compared to 2010–2019, but with only the former comparison (1990–1999 *vs* 2010–2019) bearing statistical significance ($P < 0.05$).

For liver, both post-transplant and ITT survival from 1990–1999 to 2000–2009 were reduced and statistically significant ($P < 0.05$) compared to 2010–2019. Waitlist survival from 1990–1999 and 2000–2009 was superior and statistically significant ($P < 0.05$) to 2010–2019.

For heart, waitlist survival, post-transplant, and ITT survival of patients listed from 1990–1999 to 2000–2009 were reduced and statistically different ($P < 0.05$) than patients listed in 2010–2019.

For lung, post-transplant and ITT survival from 1990–1999 to 2000–2009 were reduced and statistically significant ($P < 0.05$) when compared to 2010–2019. Waitlist survival from 1990–1999 to 2000–2009 was superior and statistically significant ($P < 0.05$) to 2010–2019.

Analysis of the effects of major changes to allocation policies showed that the kidney allocation system, heart and lung broader sharing policies, the heart 3-tiered classification system, implementation of MELD scores and hepatocellular carcinoma points, and the LAS all had statistically significant effects on ITT survival. The Kaplan–Meier Curves can be seen in Supplemental Material (Supplemental Figure 6–9 <http://links.lww.com/AOSO/A295>).

Percent Transplanted

The chi-squared test compared the percentage of transplants between the 3 decades, using 2010–2019 as a reference. The test compared the percentage of patients who had received a transplant within 3 months, 6 months, and 1 year of listing. The percentage was obtained by calculating the number of patients who received transplants in the decade divided by the total number of patients in the decade who were not listed within 3 months

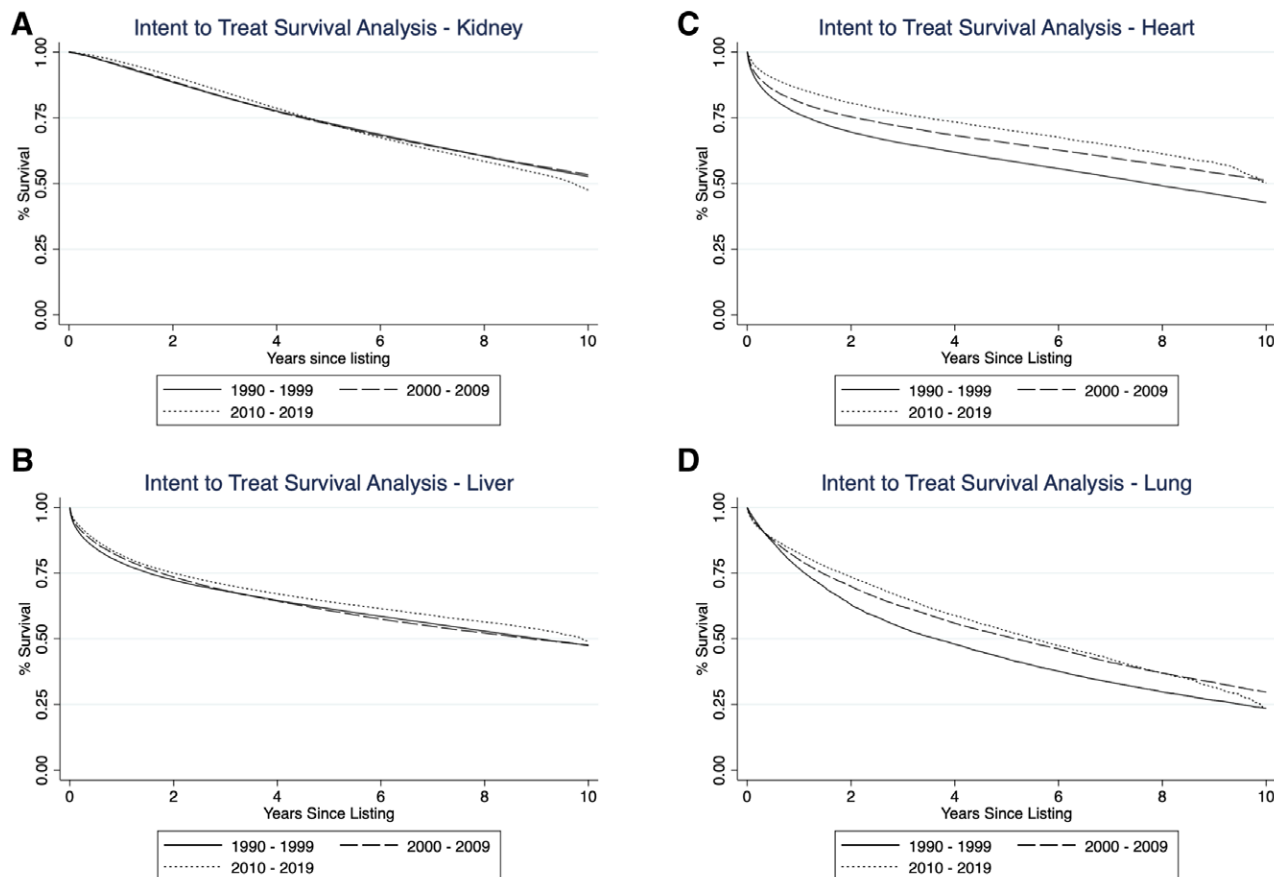


FIGURE 1. Kaplan–Meier survival function over 10 years for intent-to-treat survival in adult patients listed for (A) kidney, (B) liver, (C) heart, and (D) lung transplant.

TABLE 1.
Median Wait Time and Percentage of Patients Who Received a Transplant

Organ	Decade	Median Wait Time in Days (25th–75th Percentile)	Within 3 Months	Within 6 Months	Within 1 Year
Kidney	1990–1999	358 (137–804)	12.4%	22.5%	35.8%
	2000–2009	528 (189–1132)	7.6%	15.0%	24.3%
	2010–2019	384 (135–937)	7.9%	13.8%	21.2%
Liver	1990–1999	129 (34–342)	26.6%	37.1%	48.5%
	2000–2009	93 (20–297)	29.0%	37.7%	46.0%
	2010–2019	94 (16–270)	28.7%	36.9%	48.0%
Heart	1990–1999	107 (35–278)	30.0%	41.8%	52.9%
	2000–2009	76 (23–217)	39.3%	51.6%	62.0%
	2010–2019	87 (24–258)	35.5%	46.6%	57.4%
Lung	1990–1999	323 (133–609)	11.0%	20.0%	33.2%
	2000–2009	140 (40–394)	28.0%	38.9%	50.4%
	2010–2019	51 (15–152)	51.5%	64.1%	73.5%

Bolded = statistically significant compared to the reference era (2010–2019).

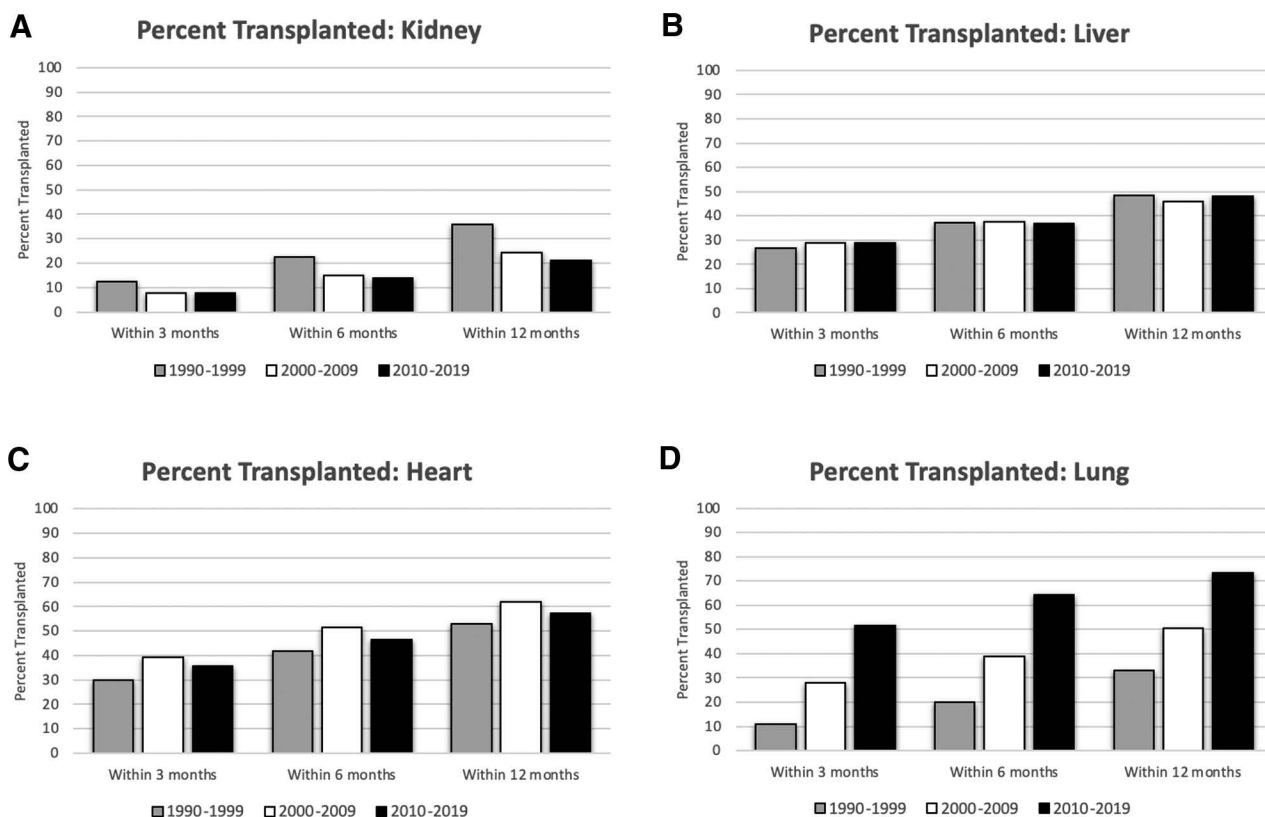


FIGURE 2. Percentage of patients transplanted for (A) kidney, (B) liver, (C) heart, and (D) lung transplant.

before the end of the study. This process was repeated for 6 months and 1 year. Table 1 and Figure 2 show the percentage of patients who received transplants at different intervals and the associated wait time.

For kidney, all comparisons of time intervals via chi-squared tests to reference decade were significant ($P < 0.05$). For kidney transplants, the percentage transplanted within 3 months was lowest during 2000–2009. The percentage transplanted within 6 months and within 1 year was lowest in the most recent decade 2010–2019. Apart from the percentage transplanted within 3 months, the most recent decade has a lower rate without an appreciable trend in median wait time.

For liver, the chi-squared test yielded statistically significant ($P < 0.05$) results for the percent transplanted in the comparison between 2010–2019 (reference decade) and 1990–1999 at the 3-month interval and 2000–2009 at the 6-month and 1-year interval. The percentage of patients transplanted within

3 months was significantly greater in the 2010–2019 decade than in the 1990–1999 decade. The percentage of patients transplanted within 6 months was greater in the 2000–2009 decade than in the 2010–2019 decade. The percentage transplanted within 1 year was significantly greater in the 2010–2019 decade than in the 2000–2009 decade. Although median waiting times in 2010–2019 decreased from the first decade, they were slightly higher than those of 2000–2009.

For heart, all comparisons of time intervals via chi-square tests to reference decade were significant ($P < 0.05$). The second decade had the highest percentage transplanted at all time intervals and the shortest median wait time. The reference decade (2010–2019) values for percent transplanted and median wait time were between those of the other 2 decades.

For lung, all comparisons of time intervals via chi-square tests to reference decade were significant ($P < 0.05$). The percentage transplanted at each time interval (within 3 months, 6

months, and 1 year) continued to increase significantly in each subsequent decade. 2010–2019 had the highest rate of percent transplanted, more than double the rates in the first comparison decade. Median wait times show a clear decreasing trend, with 2010–2019 having the lowest median wait times.

DISCUSSION

This study provides a comprehensive picture of adult transplant outcomes. Post-transplant outcomes and waitlist outcomes have been well studied, although the former has been more thoroughly examined. Post-transplant survival has steadily increased for kidney, liver, heart, and lung transplantation over the years.^{16,22–24} Similarly, several studies have shown decreased waitlist mortality for kidney and heart transplant.^{12,25–27} Our analysis confirms these findings. The goal of ITT analysis is to follow patients from listing to death, providing a more extensive picture of outcomes regardless of treatment incorporating waitlist survival, post-transplant survival, and transplant rate. Our study examines trends in ITT survival for adult kidney, liver, heart, and lung transplantation from 1990 to 2019, and reveals that ITT survival has increased steadily since 1990 for liver, heart, and lung transplant.

Similarly to pediatric kidney transplantation, waitlist and post-transplant survival have increased in adult kidney transplantation.²⁸ This is likely due to a variety of factors, such as the development of tools to predict the survival time of a transplant, yielding better matching.⁶ One of the more notable results from our study is the lack of improved ITT survival despite increases in waitlist and post-transplant survival independently. One of the likely major causes of this lack of improvement is the growing imbalance between available donor kidneys and transplant candidates. This has led to increased time spent on the waiting list compared to recent decades as shown in Table 1. Additional factors such as the increasing age of waitlist candidates and the use of more marginal deceased donor kidneys may also impact these findings.^{29,30} Waitlist survival has likely increased due to improvements in renal replacement therapy, but the continued prevalence of cardiovascular disease, malignancy, and increased numbers of patients with diabetes and high body mass index likely play an important role in the lack of improved long-term survival.^{22,29} These results highlight the importance of an ITT approach since both waitlist and post-transplant survival increased while the ITT survival in fact decreased due to a declining transplant rate.

Liver transplantation has seen consistent improvements in ITT survival, likely due to advances in immunosuppression and the use of mortality-predicting tools.^{21,31} In addition, new allocation systems have been developed with the intent to increase graft survival and waitlist survival, such as the use of the MELD score and Share 35. These new allocation policies have resulted in an increased number of patients receiving transplants, as well as a decreased probability of death.^{9,19} Despite these improvements, waitlist mortality has not improved in recent decades. The rising levels of obesity in the United States have led to an increase in the development of nonalcoholic fatty liver disease and a resulting increase in the number of patients on the waiting list.³² The proportion of older candidates on the waiting list has also increased.³³ Given that older candidates are more likely to present with comorbidities and worse disease stages, the lack of improvement in waitlist survival may partly be attributed to this increase. Since liver transplant is the most successful treatment for liver disease, the factors mentioned above make it increasingly difficult to improve waitlist mortality among adult candidates. However, ITT survival has increased overall, indicating continued improvements in liver transplant outcomes, regardless of transplant status.

For heart transplantation, both waitlist and post-transplant outcomes have been widely studied. Across eras, infection remains one of the primary causes of death.¹⁴ As with all transplants, the

increased prevalence of obesity and comorbidities likely affects ITT survival. However, the effect has not resulted in decreased survival over time. The increase in ITT survival for heart transplant is likely due to several factors. In addition to improvements in immunosuppression and transplant matching, the increased use of ventricular assist devices has resulted in increased survival for both patients on the waitlist and post-transplant patients; however, these devices are more beneficial for younger patients.^{12,13,34,35} Like liver transplant, there have been changes to heart allocation policies. Although these changes may have little effect on the waitlist survival of heart transplant candidates, they have led to less time spent on the waiting list.³⁶

Lung outcomes are less well studied when compared to other organ transplants. Unfortunately, waitlist mortality for lung transplant candidates remains the highest among all solid-organ transplants.²⁶ This finding may be due to a stronger effect of the increased prevalence of risk factors such as obesity and diabetes but also might be due to limited advancements in pretransplant interventions. The lack of improvement for waitlist survival compared to other solid organs has led to changes in lung allocation policy, in order to improve these outcomes and decrease time spent on the waitlist.²⁶ Although post-transplant survival has increased, chronic lung allograft dysfunction remains one of the major obstacles hindering long-term survival.¹⁶ There remains a need to investigate ITT survival, and although survival still lags behind other solid-organ transplants, outcomes are continuously improving regardless of treatment.

There are several common factors that have likely contributed to ITT survival for all 4 organs. Over the 30-year study period, the demographics of transplant candidates have changed across many factors. Changes in some of these factors, like age, obesity, and diagnosis, can affect the prognosis of candidates in our study period, irrespective of improvements made in treatment or allocation. Additionally, donor organ quality has changed over time for all 4 organs. Factors such as increasing age or donor obesity are a growing problem for several organs. In organs such as kidney and lung, growing supply and demand issues have resulted in more marginal organs being used for transplantation. This has led to worse donor quality overall, despite marginal changes in donor characteristics.^{23,24,29,37,38} In terms of organ allocation, many of the changes in liver, heart, and lung transplantation took place throughout the study period. Notably, the changes that accompanied the development of the new kidney allocation system, took place in 2014, near the end of the 30-year study period. Although initial data on these changes suggest some improvement in ITT survival, the effects of these changes on long-term survival may not be observed for another several years and may play a role in the lack of improvement in ITT survival currently.

Our study includes several limitations. First, we included only adult patients found in the OPTN database. Therefore, our results are not generalizable to international populations, nor are they applicable to pediatric patients. We also excluded patients who were listed for multiple organs as well as those who received previous transplants, and thus our findings may not be indicative for these patients. Although our study aims for a more comprehensive analysis of pretransplant and post-transplant outcomes, there may be several specific risk factors that influence individual outcomes for patients.

CONCLUSIONS

The demographics of adult patients listed for organ transplantation are diverse. Therefore, it is important to understand the trends in outcomes and risk factors when placing patients on the waitlist. Our study examined 813,862 patients listed for kidney, liver, heart, or lung transplantation over a 30-year period. Waitlist and post-transplant outcomes have been well-studied for these organs, but our ITT analysis aims to provide a more comprehensive picture of survival, regardless of transplant

status. Overall, ITT survival is steadily increasing for liver, heart, and lung due to factors such as continued advancements in immunosuppression and changes in organ allocation policy. Unfortunately, the continuing supply and demand issue in kidney transplant has hindered improvement in overall survival despite the relative increase in waitlist and post-transplant survival. Regarding all organs, there is room for improvement, particularly in time spent on the waitlist and efforts to reduce the socioeconomic disparities in survival. Continued evaluation of allocation policies, organ matching, and pretransplant treatment options should allow for increases in survival for all patients.

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