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The International Thoracic Organ Transplant Registry of the International Society for Heart and Lung Transplantation: Twenty-third pediatric lung transplantation report — 2020; focus on deceased donor characteristics

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In recent years, we have seen innovations in organ procurement and preservation, in post-transplant management, and in non-transplant treatments for advanced heart and lung diseases. These developments continue to influence our decisions on donor selection and the allocation of donor organs to individual recipients. The goal of this focused report is to document the changes that took place in the pediatric lung transplant donor profile over the years and to identify important donor and transplant process characteristics that influence post-transplant outcomes. This 23rd annual Pediatric Lung Transplant Report is based on the data submitted to the International Society for Heart and Lung Transplantation (ISHLT) International Thoracic Organ Transplant (TTX) Registry on 2,323 pediatric recipients of deceased donor lung transplants between January 1, 1992 and June 30, 2018. In response to a changing regulatory environment, the ISHLT Registry is undergoing an update in data acquisition, and the patient cohort examined in this report is, therefore, derived from the same data source or datasets as that examined in the 2019 annual reports.[1–4] We refer the reader to the 2019 report on pediatric lung transplantation for a detailed description of the baseline characteristics of the cohort and additional core analyses not directly related to the focus on the donor explored in this year's report. The Registry slide set available online (https://ishltregistries.org/registries/slides.asp) provides more detail, additional analyses, and other information not included in this printed report.

Methods

Data collection, conventions, and statistical methods

National and multinational transplant collectives and individual centers submit data to the ISHLT International TTX Registry. Since the Registry's inception, 481 heart transplant centers, 260 lung transplant

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centers, and 184 heart–lung transplant centers have reported data to the Registry. In our estimations, data submitted to the Registry represents approximately 80% of worldwide transplant activity.

This year's report presents an overview of donor characteristics and their association with recipient outcomes, with a focus on how the donor profile has changed over time. Because of the variation in data capturing and reporting, certain donor characteristics of clinical interest to readers, such as drug use and hypertension, cannot be provided in more detail (e.g., by region). The results reported herein seek to provide as granular detail as possible with data retained in the ISHLT International TTX Registry for transplants through June 30, 2018. With this report examining the same patient cohort as last year's, an overview of donor and recipient characteristics and outcomes is presented throughout last year's reports.[1–4] This year's Pediatric Lung Transplant Report refers to specific online electronic slides when particular data are discussed but not shown owing to space limitations; eSlide L(p) refers to the online pediatric lung transplant slides.

The ISHLT International TTX Registry website (https://ishlt.org/research-data/registries/ttx-registry) provides the detailed spreadsheets of the data elements collected in the Registry. The Registry requires submission of core donor, recipient, and transplant procedure variables at baseline (i.e., around the time of transplantation) and at yearly follow-up, and these variables, therefore, have low rates of missingness. Nevertheless, data quality depends on the accuracy and completeness of reporting. Rates of missingness may significantly increase for Registry variables that depend on voluntary reporting. However, the Registry uses various quality control measures to ensure acceptable data quality and completeness before including data for analyses.

Analytic conventions

For this year's report, analyses of pediatric lung transplants do not include combined heart–lung transplant data. In addition, the Registry does not capture the exact occurrence date for most secondary outcomes (e.g., bronchiolitis obliterans syndrome [BOS]), but it does capture the window of occurrence (e.g., the event occurred between the first- and the second-year annual follow-up visits). For the report's analyses, we use the midpoint between the annual follow-ups as a surrogate for the event date. On the follow-up where a death is reported, some underreporting of secondary outcomes and other information is highly probable. Thus, to reduce the potential of underestimating event rates or other outcomes, we restrict some analyses to include only surviving recipients. For time to event, we censor the follow-up of recipients who do not experience the event of interest; the recipient was reported not to have had the event the last time they were spoken to, which would either be the most recent annual follow-up or the time of retransplantation. We truncate time-to-event graphs (e.g., survival graphs) when the number of individuals at risk becomes <10. Previous Registry report themes provide more details regarding specific donor and recipient characteristics and outcomes.[5–9] With univariate analyses only being performed for this report, results should be taken with caution without drawing strong inferences from the survival data.

The Registry Steering Committee selected deceased donor characteristics as the theme topic for the 2020 report. With last year's report focusing on donor and recipient size match, this year's report concentrated on changes in donor characteristics to build upon the previous work to improve our understanding of donor selection to enhance outcomes for pediatric lung transplant recipients.

Although there are accepted criteria for donor lungs,[10] there is surprisingly little literature outlining current practice and the impact of donor characteristics on lung transplantation outcomes, especially in children. Owing to the paucity of organ donors and the rising number of patients requiring lung transplantation, clinicians often have to accept lungs from donors with a wide range of characteristics and clinical scenarios that can be challenging, especially with the urgent need to make an important decision of accepting donor organs for transplantation. Therefore, this year's Registry report focuses on an overall theme of deceased donor characteristics.

Results

Deceased donor characteristics

With an objective to assess deceased donor characteristics, we examined associations of these changes with outcomes. Table 1 outlines the characteristics of donors for pediatric lung transplant recipients between January 1992 and June 2018, unless otherwise noted in the table. By era, donor age has increased, with more donors being female. Concurrently, with rising donor age over these same eras, donor height and donor body mass index increased. Moreover, donor cause of death has undergone changes by era with more donors dying of anoxia and fewer dying from head trauma in the modern era. Not surprisingly, there have been no significant changes in donor blood type by era. Our assessment of the remaining donor characteristics found no significant trends.

Figure 1 (eSlides L[p] 6) illustrates the trends of increasing donor age and increasing donor body mass index between January 1992 and June 2018 by center locations, whereas there is no change in donor partial pressure of oxygen (PO_2). Figure 2 (eSlides L[p] 7) shows that the recent rise in female donors is more pronounced in Europe than in North America or other regions (e.g., South America, Asia, the Middle East, Australia, and others). Changes in donor cause of death are more diverse across eras for all locations (Europe, North America, and other) as shown in Figure 3 (eSlides L[p] 8). In the modern era, donor death caused by anoxia increased in Europe and North America, whereas head trauma as a cause of donor death decreased in all the 3 geographic locations, with more pronounced reductions in Europe and other regions. In Europe, motor vehicle fatalities from head trauma have dramatically declined between the 1990s and 2010s,[11] which explains our findings. Although there was a reduction of head trauma as a donor cause of death in North America, it was not as prominent as in Europe and other regions. The cause of death categorized as other increased in both Europe and other regions.

Owing to a paucity of organs, donors with previous smoking use may be accepted for pediatric patients requiring lung transplantation. For recipients aged 11–17 years and donors aged ≥11 years, Figure 4a (eSlides L[p] 9) shows that the proportion of children receiving lungs from donors with a smoking history is declining. There has been little change with respect to donor alcohol use since January 2005 (Figure 4b) (eSlides L[p] 9); however, data are only available for this most recent era. Owing to the small number of pediatric lung transplant donors with certain characteristics such as alcohol and cocaine use these variables were excluded from the survival analysis.

Table 1 Donor Characteristics by Era (Transplantations: Jan 1, 1992–June 30, 2018)

Characteristics	Jan 1992–Dec 2000 (N = 592)	Jan 2001–Dec 2009 (N = 824)	Jan 2010–June 2018 (N = 907)	*p*-value
Geographic location				<0.0001
Europe, *n* (%)	188 (31.8)	312 (37.9)	395 (43.6)	
North America, *n* (%)	391 (66.0)	457 (55.5)	417 (46.0)	
Other, *n* (%)	13 (2.2)	55 (6.7)	95 (10.5)	
Age, years	11 (0–46)	15 (1–52)	16 (0–54)	<0.0001
Male, *n* (%)	312 (54.0)	383 (46.5)	399 (44.0)	0.0007
Height (cm)	144.0 (65.0–178.0)	157.0 (72.0–180.0)	157.5 (72.0–180.0)	<0.0001
BMI (kg/m^2)	18.9 (13.0–26.0)[a]	20.3 (13.6–29.1)	20.9 (13.3–32.9)	<0.0001
Blood type, %				
A	34.5	32.9	32.6	0.7749
AB	1.8	1.3	1.7	
B	7.7	7.5	6.2	
O	56.0	58.3	59.5	
Cause of death, %				
Anoxia	9.6	14.2	24.8	<0.0001
CVA/stroke	23.0	31.3	28.2	
Head trauma	54.6	49.4	38.4	
Other	12.8	5.1	8.5	
CMV antibody positive, %	49.6	54.7	54.5	0.2497
EBV antibody positive, %	—	77.5[b]	77.8	0.9409
Hep B antibody positive, %	1.1	1.1	0.5	0.5605
Hep C antibody positive, %	0	0%	0	—
Smoking history, %	9.0	6.0	5.0	0.0948
Alcohol use, %	—	2.1[c]	3.5	0.2323
Cocaine use, %	—	3.7	2.5	0.2921
Other drugs use, %	—	12.1	12.3	0.9119
Hypertension, %	2.1[d]	1.6	2.2	0.8219
Diabetes, %	3.7[d]	5.6	6.0	0.3696
PO_2 (mmHg)	—	431.0 (108.0–585.0)[e]	423.5 (107.0–571.0)	0.2155

Abbreviations: BMI, body mass index; CMV, cytomegalovirus; CVA, cerebrovascular accident; Dec, December; EBV, Epstein Barr virus; Hep, hepatitis; Jan, January; PO_2, partial pressure of oxygen.

Summary statistics excluded transplants with missing data.

Continuous factors are expressed as the median (5^{th} – 95^{th} percentiles).

Comparisons for categorical variables were made using chi-square statistic.

Comparisons for continuous variables were made using the Wilcoxon's rank-sum test.

[a]Based on April 1994–Dec 2000 transplantations.

[b]Based on April 2006–Dec 2009 transplantations.

[c]Based on July 2004–Dec 2009 transplantations.

[d]Based on April 1994–Dec 2000 transplantations.

[e]Based on Jan 2005–Dec 2009 transplantations.

Survival

Survival within 12 months of transplantation

To determine how deceased donor characteristics influenced short-term post-lung transplant survival in children, we used univariate analysis with Kaplan–Meier curves to assess survival within 12 months of transplantation. We did not identify a statistically significant association between donor age and survival within 12 months after lung transplantation in pediatric recipients; however, the number of donors in the ≥18-year age group was small (Figure 5) (eSlides L[p] 12). Our analysis further explored donor and recipient age interactions and donor age and location interactions. Figure 6 (eSlides L[p] 13) shows that donor age had no significant effect on the survival for either the recipients aged 0–10 years or those aged 11–17 years. Moreover, donor age had no significant effect on survival for recipients transplanted in Europe, North America, or other regions (Figure 7) (eSlides L[p] 14).

The causes of death of donors have been evolving over the past 3 decades as illustrated in Figure 3 (eSlides L[p] 8), but these changes appear to have had only a small impact on the 12-month survival of children after lung transplantation. Figure 8 outlines the effect of donor cause of death and donor arterial PO_2 on survival (eSlides L[p] 15). Although donor PO_2 is commonly used as a surrogate measure of donor lung quality, our analysis found that donor PO_2 did not affect survival at 12 months for pediatric lung transplant recipients (Figure 8b) (eSlides L[p] 15). Importantly, the different PO_2 donor groups only comprise donor lungs that were transplanted. For recipients aged 11–17 years who received lungs from donors aged ≥11 years, Figure 9 (eSlides L[p] 16) shows that a history of smoking

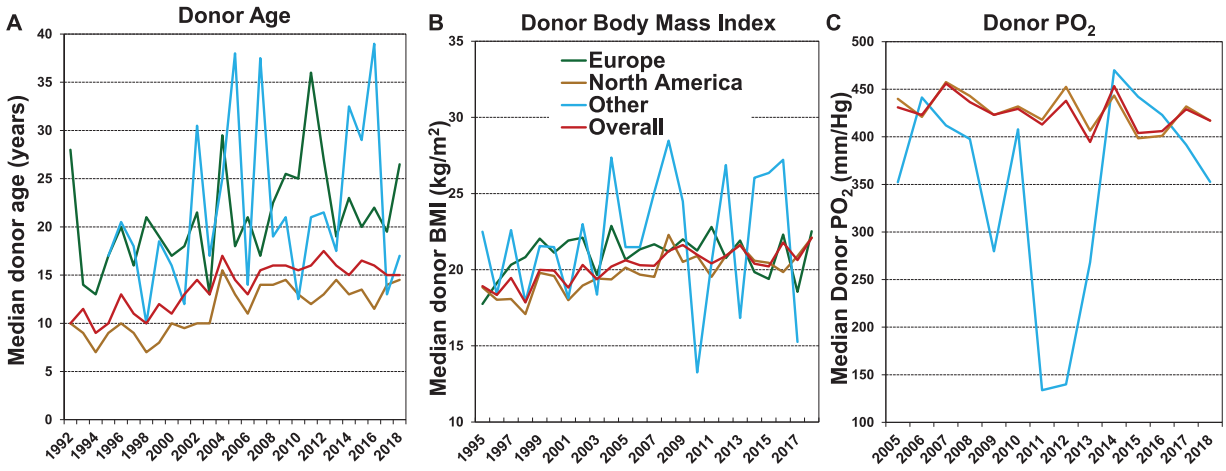

Figure 1 Median donor (a) age (years), (b) BMI (kg/m^2), and (c) PO_2 (mm Hg) by year and geographic location (transplantations: January 1992−June 2018). BMI, body mass index; PO_2, partial pressure of oxygen.

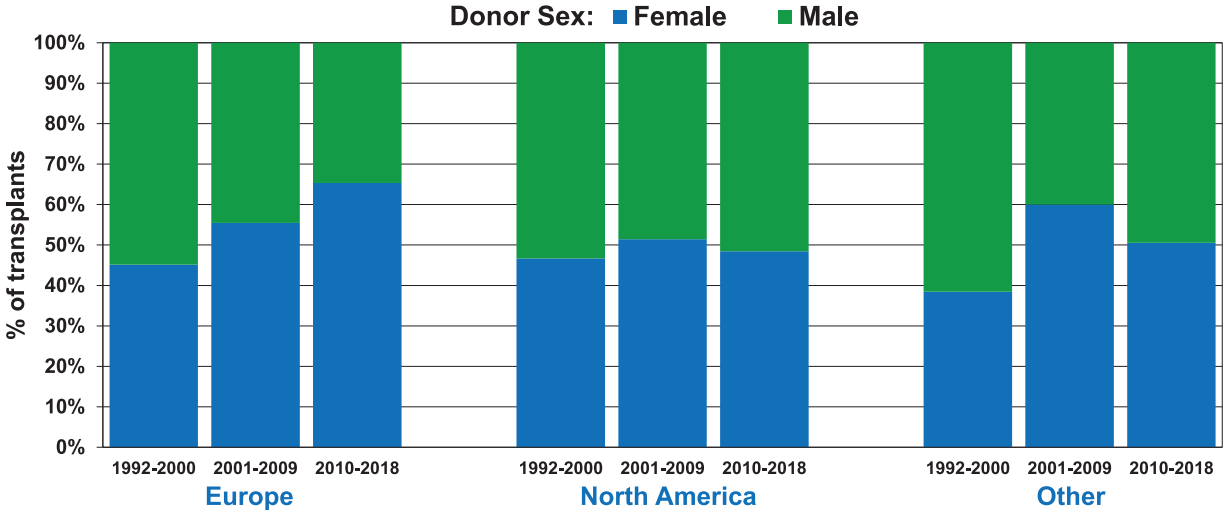

Figure 2 Donor sex distribution by geographic location and era (transplantations: January 1992−June 2018).

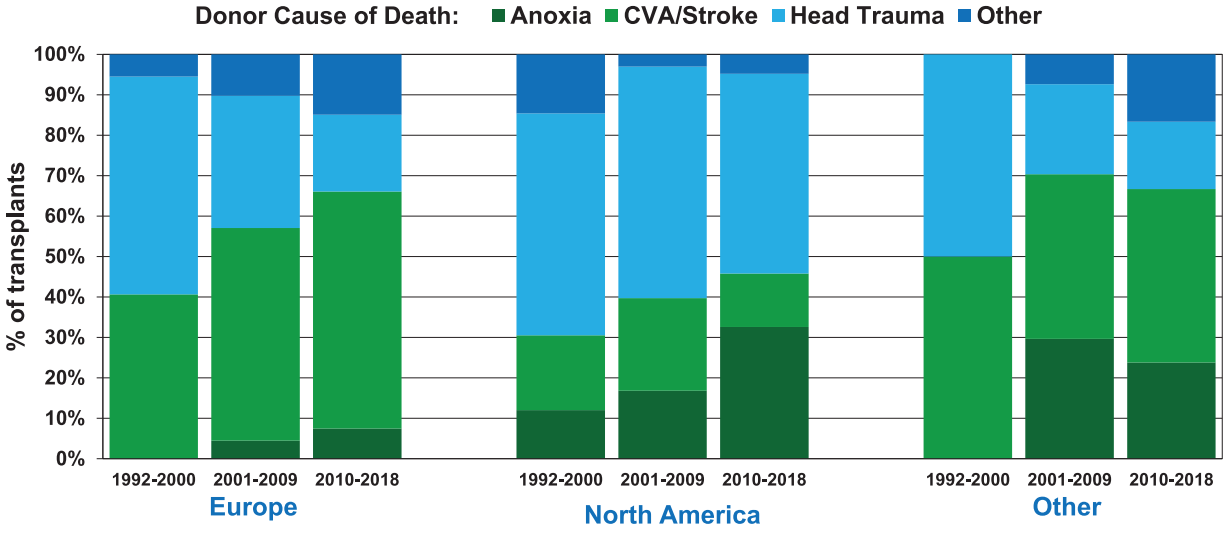

Figure 3 Donor cause of death distribution by geographic location and era (transplantations: January 1992−June 2018). CVA, cerebrovascular accident.

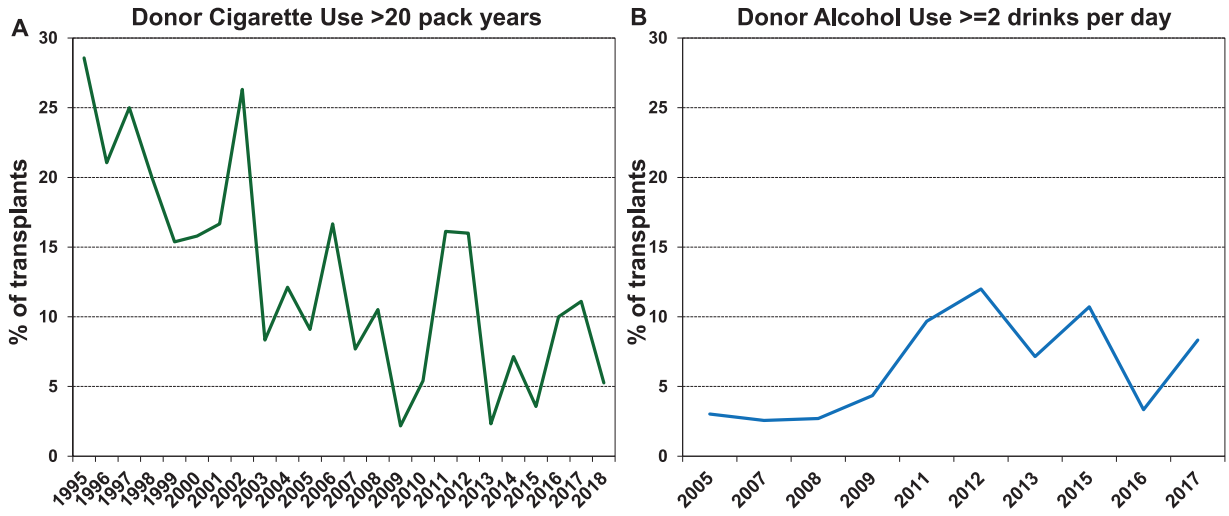

Figure 4 Percentage of donors with a history of (a) smoking and (b) alcohol use—for recipients aged 11–17 years and donors aged ≥11 years—by year (transplantations: January 2005–June 2018).

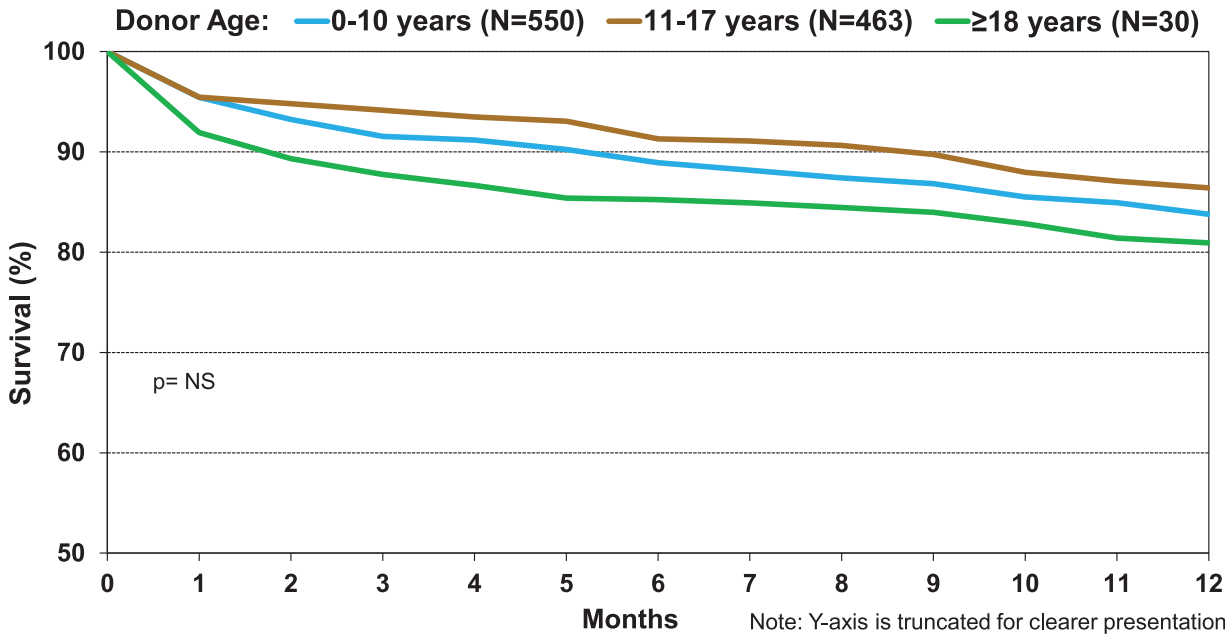

Figure 5 Kaplan–Meier survival within 12 months by donor age (transplantations: January 2000–June 2017). NS, non-significant.

in the donors did not influence the 12-month survival after lung transplantation. In pediatric recipients, the most common form of donor substance abuse was other drug use, defined as the use of non-intravenous street drugs such as crack, marijuana, or prescription narcotics, sedatives, hypnotics, or stimulants (Table 1). Our analysis found no effect on short-term survival in the sub-group of pediatric lung transplant recipients who received organs from donors with this social history (Slides L[p] 17).

Further analysis investigating the effect of deceased donor characteristics on outcomes demonstrated that an ischemic time of <4 hours was associated with worse 12-month survival compared with that of ≥4 hours of ischemic time after lung transplantation in children (Figure 10) (eSlides L[p] 18). This finding is consistent with the 2017 ISHLT Registry Report[12] and other studies[13,14] using univariate and multivariable analyses. With the rising donor age in pediatric lung transplant recipients (Table 1), we examined the interaction of donor age with ischemic time and found no association between ischemic time (<4 hours or ≥4 hours) and 12-month survival (Figure 11) (eSlides L[p] 19). We further explored the interaction of donor PO_2 with ischemic time and found no correlation (Figure 12) (eSlides L[p] 20).

Survival within 5 years of transplantation conditional on survival to 1 year

To explore the effect of deceased donor characteristics on long-term post-lung transplant survival in children, we used univariate analysis with Kaplan–Meier survival curves to determine survival within 5 years of transplantation conditional on survival to 1 year. Figure 13 (eSlides L[p] 22)

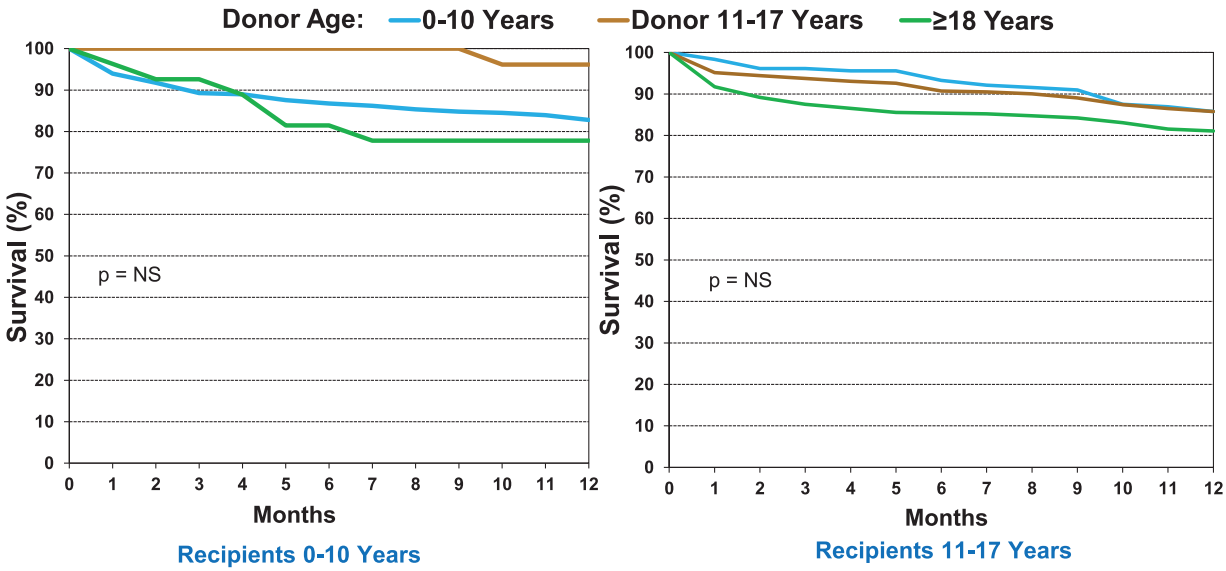

Figure 6 Kaplan–Meier survival within 12 months by donor and recipient ages (transplantations: January 2000–June 2017). NS, non-significant.

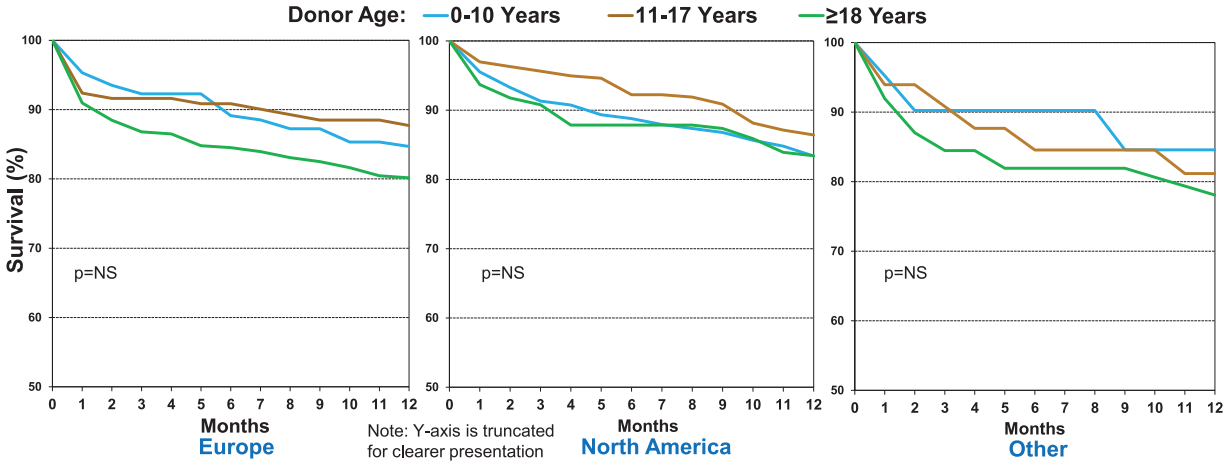

Figure 7 Kaplan–Meier survival within 12 months by donor age and geographic location (transplantations: January 2000–June 2017). NS, non-significant.

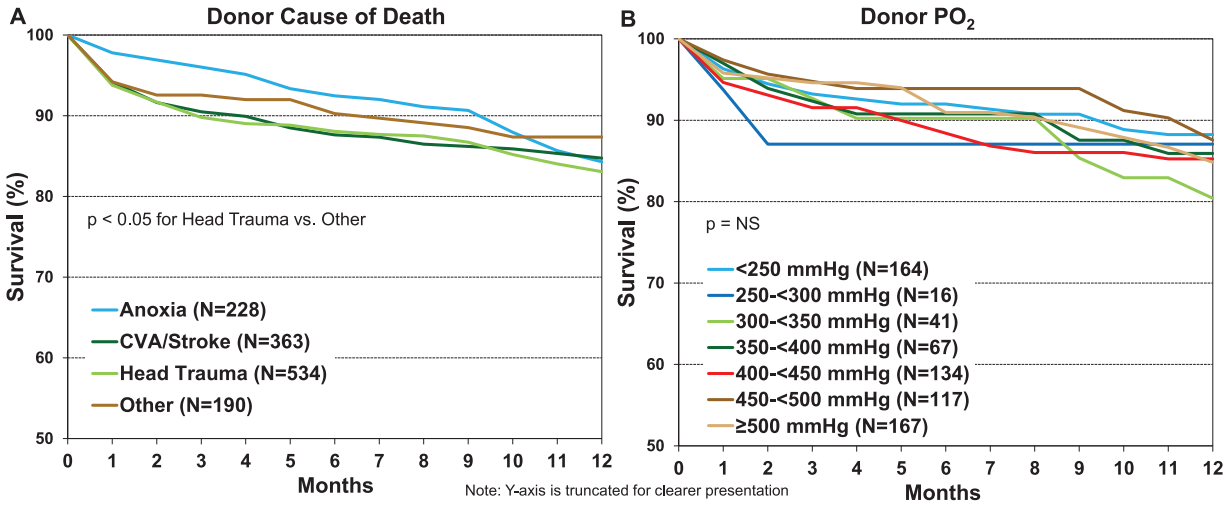

Figure 8 Kaplan–Meier survival within 12 months by (a) donor cause of death (transplants: January 2000–June 2017) and (b) donor PO_2 (transplantations: January 2005–June 2017). CVA, cerebrovascular accident; NS, non-significant; PO_2, partial pressure of oxygen.

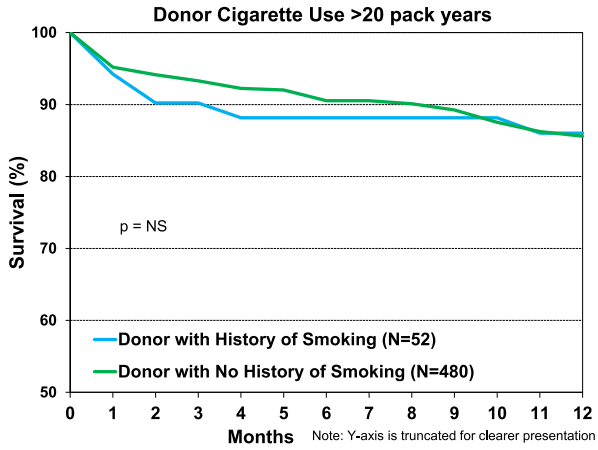

Figure 9 Kaplan–Meier survival within 12 months for recipients aged 11–17 years and donors aged ≥11 years by donor history of smoking (transplantations: January 2000–June 2017). NS, non-significant.

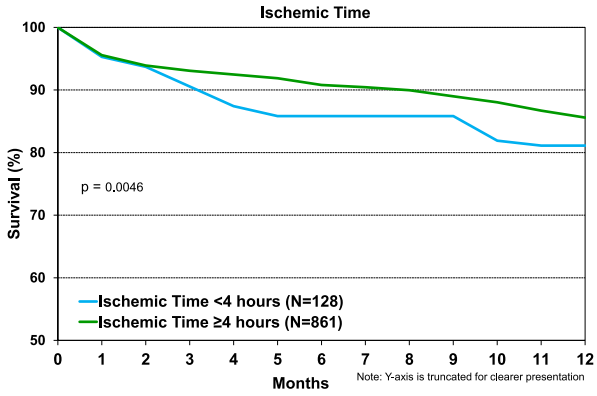

Figure 10 Kaplan–Meier survival within 12 months by ischemic time (transplantations: January 2000–June 2017).

shows a long-term survival advantage associated with donor age of 0–10 years compared with the age of 11–17 years. We then examined donor and recipient age interactions and found no associations impacting survival (Figure 14) (eSlides L[p] 23). Researching for donor age and geographic location interaction, we found that receiving organs from a younger donor was associated with significantly improved long-term outcomes in North America, whereas in Europe or Other regions, the differences did not reach statistical significance (Figure 15) (eSlides L[p] 24).

Similar to the short-term survival analysis, the donor cause of death did not have a large impact on long-term survival (Figure 16a) (eSlides L[p] 25). Moreover, we found that donor PO_2 did not affect long-term survival in pediatric lung transplant recipients (Figure 16b) (eSlides L[p] 25). Regarding donor history of substance use, there was no significant long-term survival impact on pediatric lung transplant recipients by donor history of smoking (eSlides L[p] 26) or donor history of other drug use (eSlides L[p] 27).

Given our finding of an association between ischemic time and 12-month survival, we investigated whether there was a similar association between ischemic time and long-term survival, comparing <4 hours and ≥4 hours of ischemic time. Likewise, a shorter ischemic time was associated with lower survival (Figure 17) (eSlides L[p] 28). In contrast to the 12-month survival analysis, we found that younger donor age was associated with better long-term survival in the ≥4-hour ischemic time cohort (Figure 18) (eSlides L[p] 29). The influence of donor age on post-transplant outcomes has been widely studied in adult lung transplant recipients, with older donors not affecting survival in older recipients but negatively affecting younger recipients.[15] This topic merits further study in dedicated analyses.

Freedom from BOS conditional on survival to discharge

We examined freedom from BOS conditional on survival to discharge by donor age. As depicted in Figure 19 (eSlides L[p] 31), donor age did not affect freedom from BOS in pediatric lung transplant recipients. The analysis investigating

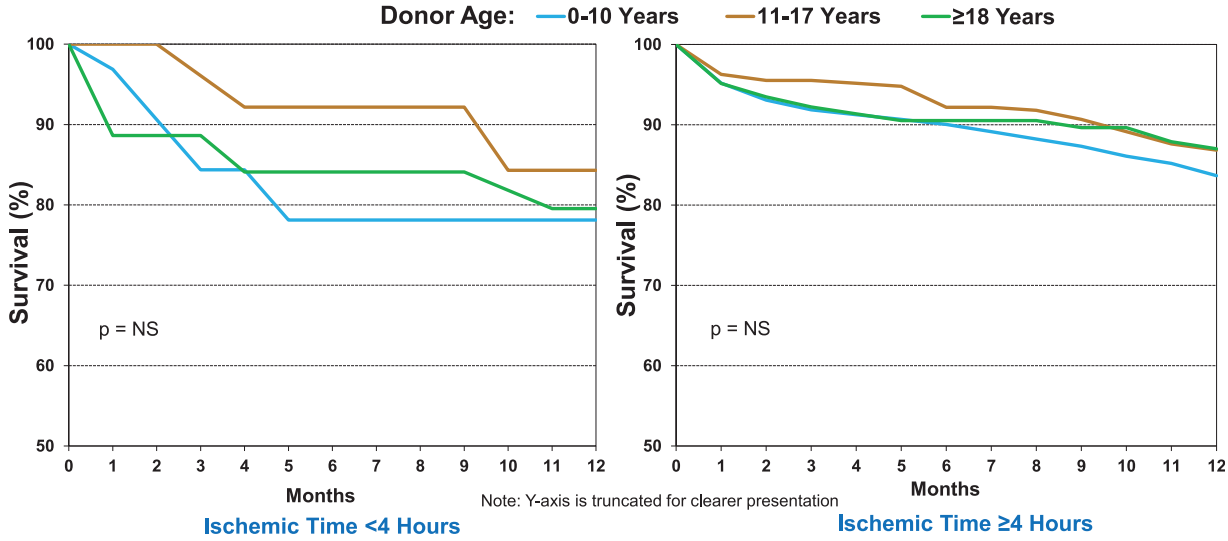

Figure 11 Kaplan–Meier survival within 12 months by ischemic time and donor age (transplantations: January 2000–June 2017). NS, non-significant.

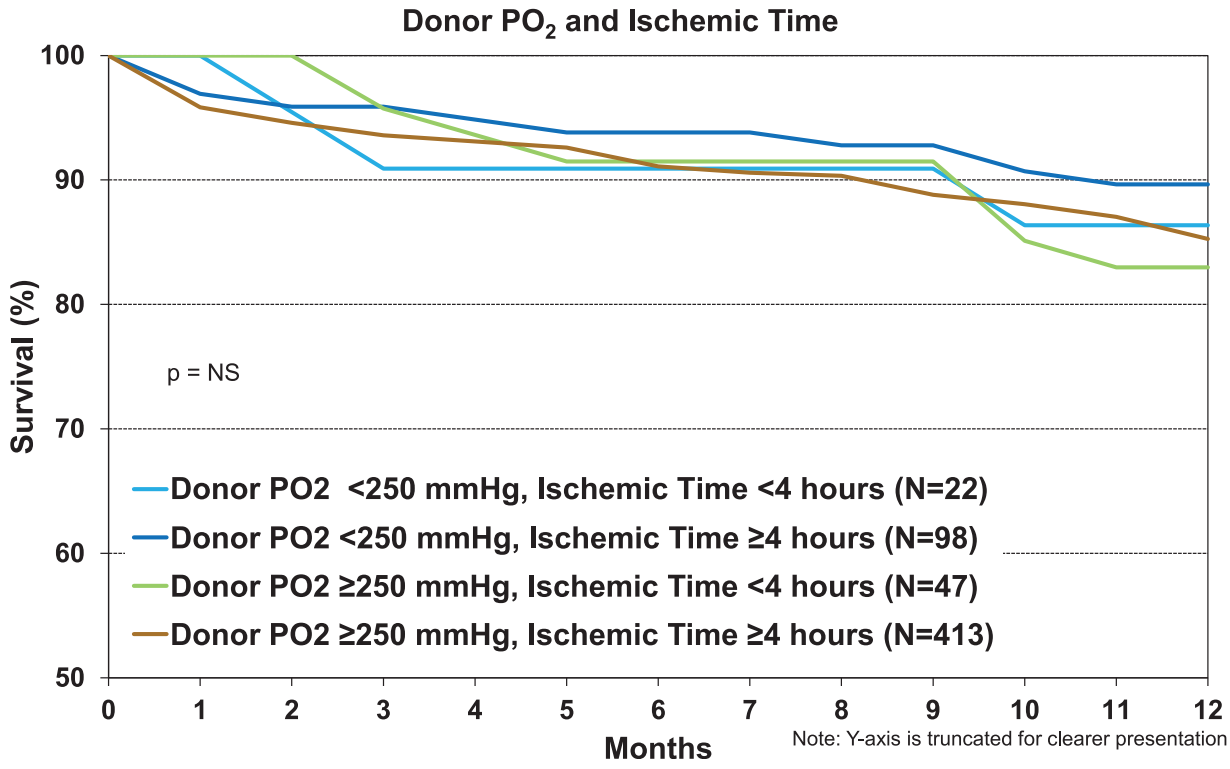

Figure 12 Kaplan–Meier survival within 12 months by donor PO_2 and ischemic time (transplantations: January 2005–June 2017). NS, non-significant; PO_2, partial pressure of oxygen.

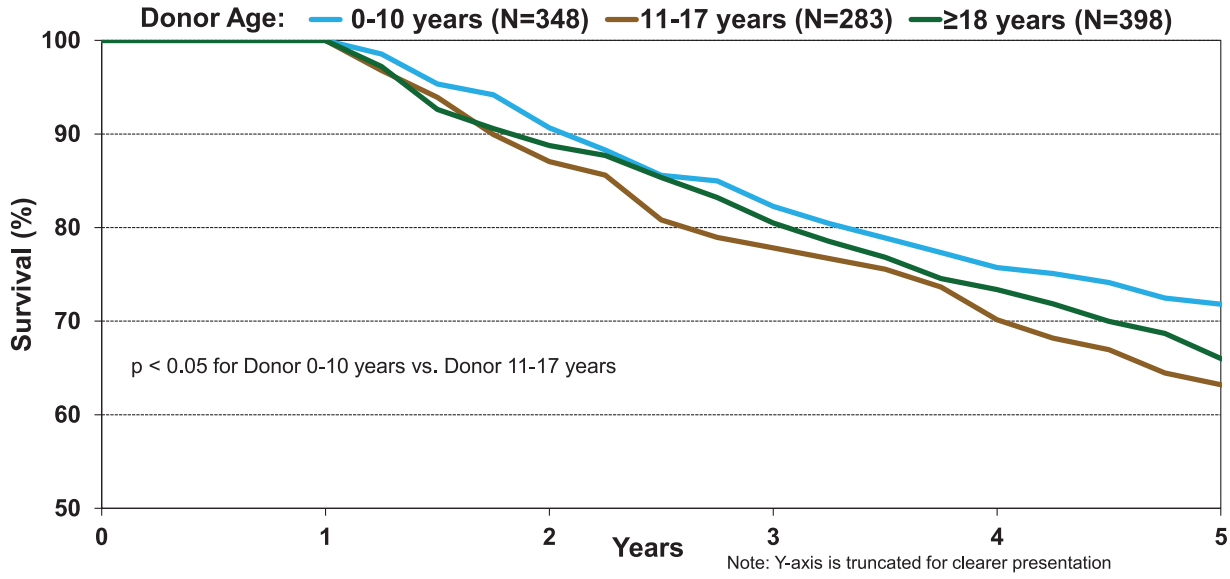

Figure 13 Kaplan–Meier survival within 5 years conditional on survival to 1 year by donor age (transplantations: January 2000–June 2013).

the impact of donor cause of death on freedom from BOS did not show significant differences short of a higher freedom from BOS in a small group of patients whose donor cause of death was listed as other, compared with those whose causes of death were head trauma and cerebrovascular accident/stroke (Figure 20a) (eSlides L[p] 32. Notably, donor PO_2 did not impact freedom from BOS (Figure 20b) (eSlides L[p] 32). Finally, we examined the effect of ischemic time on freedom from BOS conditional on survival to discharge and found no association (Figure 21) (eSlides L[p] 33).

Conclusions

Building on last year's report, the 2020 ISHLT International TTX Registry Report on pediatric lung transplantation provides an update on key factors related to deceased donor characteristics. As we experience continued

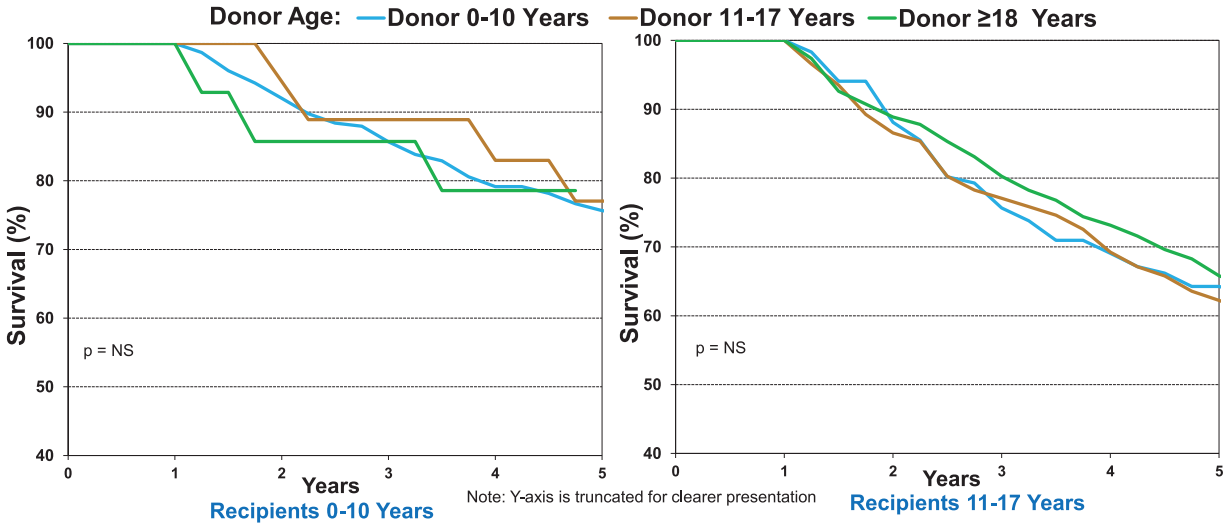

Figure 14 Kaplan–Meier survival within 5 years conditional on survival to 1 year by the recipient and donor ages (transplantations: January 2000–June 2013). NS, non-significant.

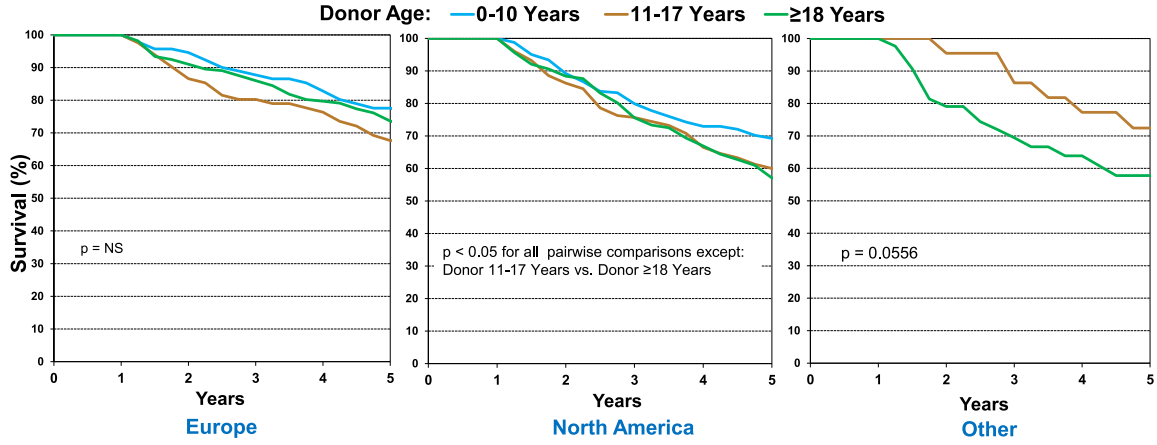

Figure 15 Kaplan–Meier survival within 5 years conditional on survival to 1 year by geographic location and donor age (transplantations: January 2000–June 2013). NS, non-significant.

Note: There was no sufficient number of transplantations from donors 0 to 10 in other location.

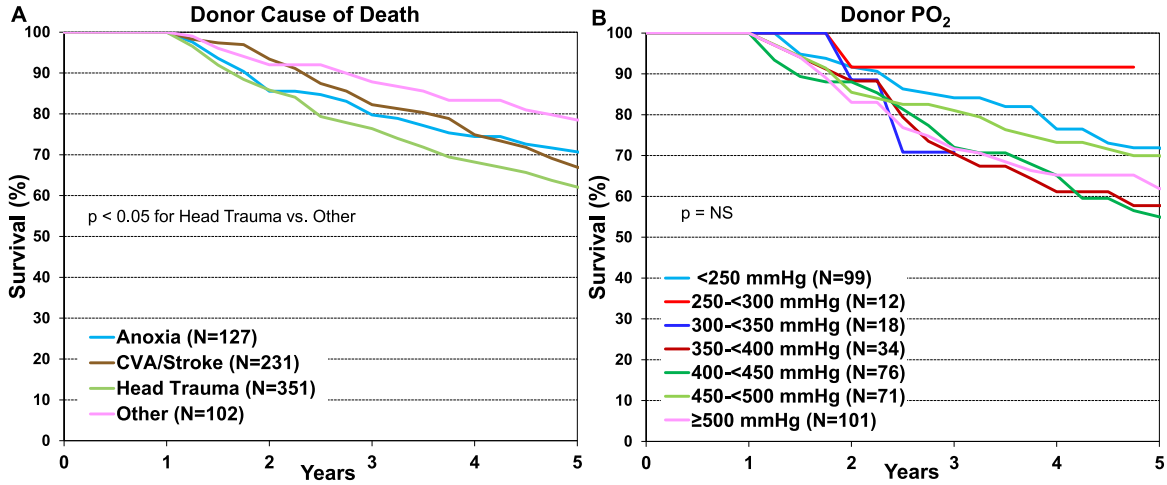

Figure 16 Kaplan–Meier survival within 5 years conditional on survival to 1 year by (a) donor cause of death (transplantations: January 2000–June 2013) and (b) donor PO_2 (transplantations: January 2005–June 2013). CVA, cerebrovascular accident; NS, non-significant; PO_2, partial pressure of oxygen.

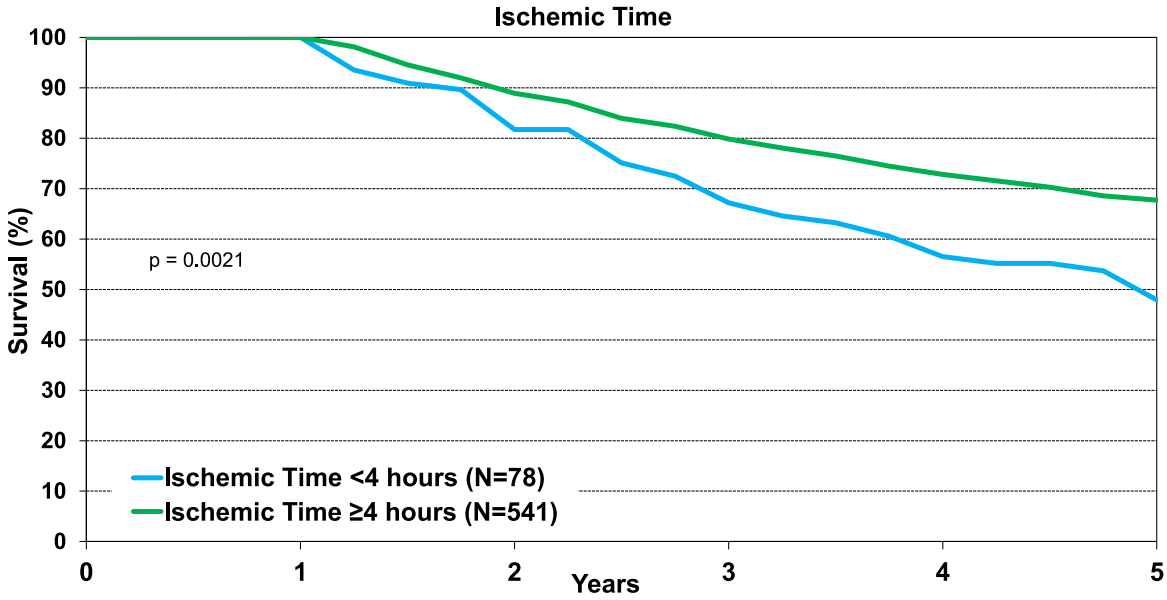

Figure 17 Kaplan–Meier survival within 5 years conditional on survival to 1 year by ischemic time (transplantations: January 2000–June 2013).

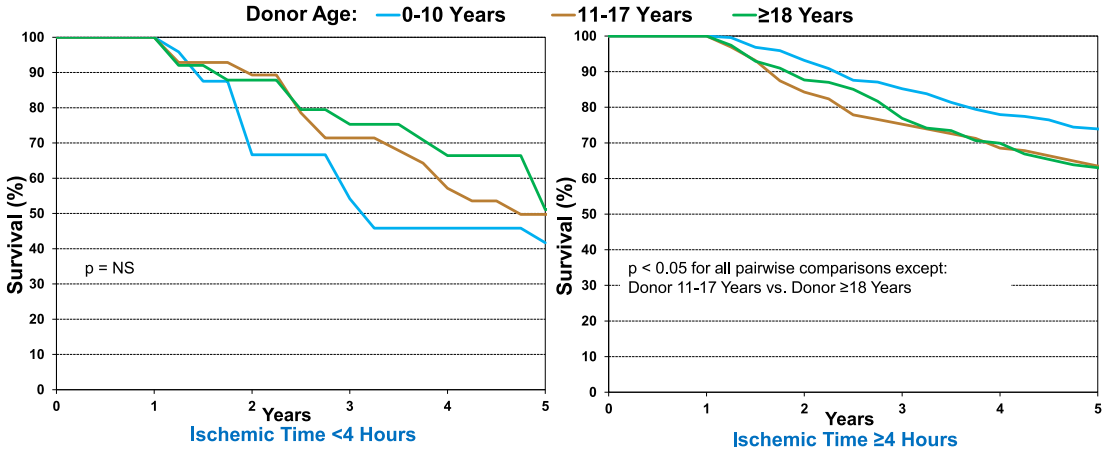

Figure 18 Kaplan–Meier survival within 5 years conditional on survival to 1 year by ischemic time and donor age (transplantations: January 2000–June 2013). NS, non-significant.

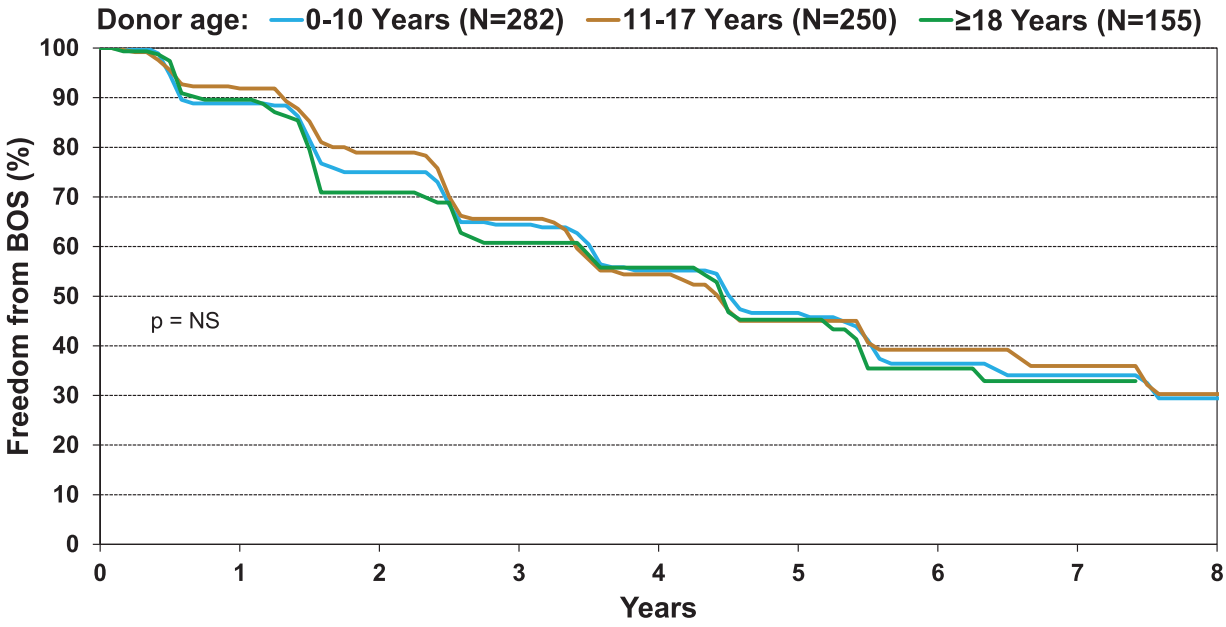

Figure 19 Freedom from BOS conditional on survival to discharge by donor age (transplantations: January 2000–June 2017). BOS, bronchiolitis obliterans syndrome; NS, non-significant.

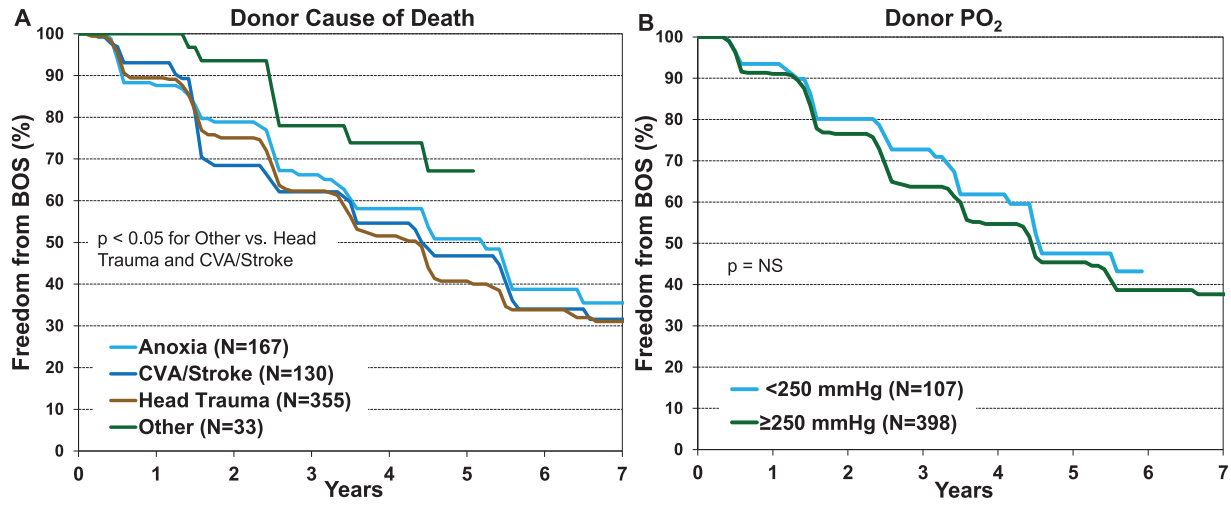

Figure 20 Freedom from BOS conditional on survival to discharge by (a) donor cause of death (transplantations: January 2000−June 2017) and (b) donor PO_2 (transplantations: January 2005−June 2017). BOS, bronchiolitis obliterans syndrome; CVA, cerebrovascular accident; NS, non-significant; PO_2, partial pressure of oxygen.

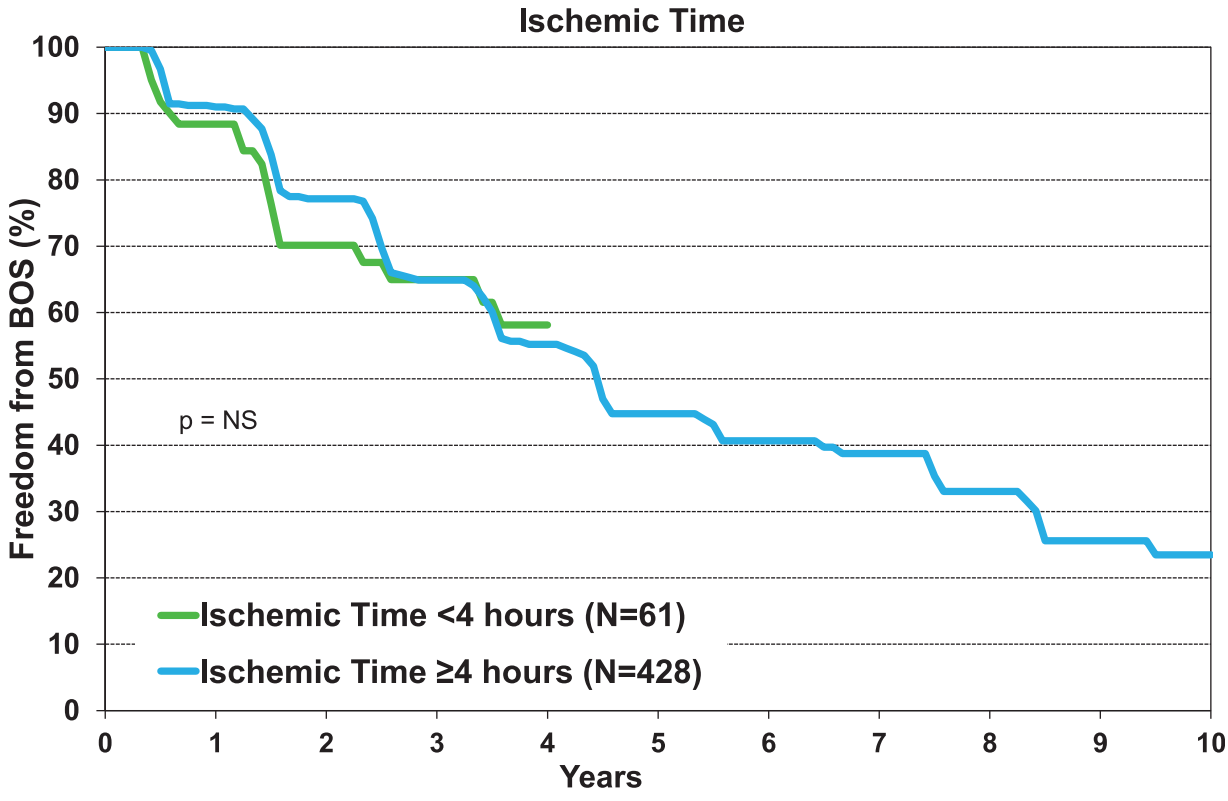

Figure 21 Freedom from BOS conditional on survival to discharge by ischemic time (transplantations: January 2000−June 2017). BOS, bronchiolitis obliterans syndrome; NS, non-significant.

improvements in the survival of children after lung transplantation, it is essential to examine all facets of the transplantation process to facilitate further advancements. Owing to the small sample size, these results should be interpreted with caution even if we found statistical significance. Despite this limitation, this year's report provides insight into important variables to make decisions on donor selection, which can help clinicians with limited available evidence on this very important topic. With the evidence presented here, we believe the donor pool for children listed for lung transplantation could be further expanded.

Disclosure statement

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