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The Registry of the International Society for Heart and Lung Transplantation: Twentieth Pediatric Heart Transplantation Report—2017; Focus Theme: Allograft Ischemic Time

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Pediatric heart transplantation is performed throughout the world and the annual number of transplants has grown dramatically since the first transplant was performed in 1967. The Registry of the International Society for Heart and Lung Transplantation (ISHLT) is the largest source of worldwide heart transplant data with almost 14,000 transplants in children reported. As such, the Registry is able to examine temporal trends in the management and outcomes of pediatric heart transplant recipients.

Statistical methods

Data collection, conventions and statistical methods

National and multinational organ/data exchange organizations and individual centers submit data to the ISHLT Registry. Since its inception, 472 heart transplant centers, 256 lung transplant centers and 180 heart–lung transplant centers have reported data to the Registry. In our

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estimations, data submitted to the Registry represent approximately three quarters of worldwide transplant activity.

An overview of donor and recipient characteristics and outcomes is presented in this report. The data are supplemented with additional and extended analyses presented in the online slide sets (3 separate slide sets, named "Introduction," "Heart Overall" and "Heart Pediatric"; see http://ishlt.org/registries/slides.asp?slides=heartLungRegistry/). Slide sets for previous annual reports are also available on this site. The study refers to specific online e-slides when particular data are discussed but not shown in the report due to space limitations; e-slide numbers refer to the online (Pediatric Heart Transplant slide set [eSlide H(p)].

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

Analytical conventions

Unless otherwise specified, heart-lung transplants are not included in analyses of heart transplants or lung transplants. Retransplant includes those with a previously reported transplant of the same organ type, same organ type in combination, or with a retransplant diagnosis. Because identification of all transplants for an individual may not be complete, the number of retransplant events may be slightly underestimated. The Registry does not capture the exact occurrence date for most secondary outcomes (e.g., renal dysfunction), but it does capture the window of occurrence (i.e., the event occurred between the first- and the second-year annual follow-up visits). For the annual report, the mid-point between annual followups is used as a surrogate for the event date. There is some bias in reporting secondary outcomes and other information on the follow-up where a death is reported. To reduce the possibility of underestimating event rates or other outcomes, some analyses are limited to surviving patients. For time-to-event rates and cumulative morbidity rates, follow-up of recipients not experiencing the event of interest was censored at the last time the recipient was reported not to have had the event, either the most recent annual follow-up or the time of retransplantation. Time-to-event graphs (e.g., survival graphs) are truncated when the number of individuals still at risk was <10. Additional information regarding the general statistical methods used for analyses and data interpretation is included in the Supplementary Material available online (www.ishltonline.org).

Focus theme methods: Allograft ischemic time

The Registry Steering Committee selected allograft ischemic time as the theme topic for the 2017 report. Allograft ischemic time was defined as the time elapsed between aortic cross-clamp performed during organ procurement surgery and coronary artery reperfusion during heart transplant surgery.

The reporting of allograft ischemic time significantly varied by geographic region, with high rates of data completeness from North American transplant centers, low rates of completeness from European centers and moderate rates for centers from other regions. Thus, we recommend cautious interpretation of the theme data, especially for analyses that include geographic region and for generalizability to non–North American centers. The inconsistent reporting of different variables from different regions illustrates the trade-offs between worldwide broadly generalizable Registry data versus more internally valid but less generalizable data collected locally or regionally.

Pediatric heart transplant—overview of donor and recipient demographics, survival and morbidity outcomes

Centers and activity

The number of centers reporting pediatric heart transplants (age <18 years old at the time of transplant) has been

relatively stable over the last several years, with 120 centers reporting at least 1 transplant in 2015 (Figure 1, eSlide H(p) 4). The majority (>85%) have been reported from Europe and North America. The annual number of transplants reported to the Registry has increased with 414 reported in 2000 and 684 reported in 2015 (eSlide H(p) 10). Most centers are relatively low-volume centers, averaging 1 to 4 pediatric heart transplants per year, whereas the number of centers averaging > 10 transplant per year increased from 15 in 2004 to 2008 to 22 in 2009 to June 2016 (eSlide H(p) 5). Centers averaging <10 transplants per year account for the majority of transplants in Europe, whereas centers averaging ≥ 10 transplants per year account for >60% of the transplants from North America. Outside of Europe and North America, nearly 80% of transplants are performed by centers that average 1 to 4 transplants per year (Figure 2, eSlide H(p) 8).

Recipient characteristics

Consistent with previous reports, infants (age <1 year at transplant) have continued to account for the greatest number of transplants, with >1,600 infant transplants reported to the Registry from 2004 to June 2016 (eSlide H(p) 9). There were geographic differences with proportionally more infants being transplanted in North America and fewer infants being transplanted outside of Europe and North America (eSlide H(p) 11). Congenital heart disease (CHD) was the underlying diagnosis leading to transplant in the majority of infants (55%), whereas cardiomyopathy was the most common diagnosis among adolescents (age 11 to 17 years at transplant) (Figure 3, eSlides H(p) 16 to 19). The percentage of retransplants has been relatively stable over time, comprising 5% of all pediatric heart transplants in 2015 (eSlide H(p) 103). Most retransplants occurred at > 60 months from the primary transplant and occurred among patients >5 years old (eSlide H(p) 104). Indication for transplant was the focus theme of the 2016 Registry report and additional details on the underlying diagnoses can be found in that report.¹

The utilization of mechanical circulatory support (MCS) has continued to be common as a bridge to transplant, with ventricular assist devices (VADs) being the primary support modality. The overall utilization differed by age and by underling disease (Figure 4, eSlides H(p) 23 to 25). Among patients with dilated cardiomyopathy (DCM), >50% of non-infants were bridged to transplant on some form of MCS, with most patients being supported with a VAD. Among patients with CHD, the utilization of MCS was less common, especially among infants. Only 12% of infants with CHD were bridged to transplant on some form of MCS, with extracorporeal membrane oxygenation (ECMO) use being more common than VAD use in this group.

Sensitization has continued to be an important issue in pediatric heart transplant recipients. Patients with CHD were more likely to have some degree of sensitization compared with DCM, defined as a panel-reactive antibody (PRA) level of $\geq 10\%$, approaching nearly 40% in adolescents (Figure 5,

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