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Pediatric heart-liver transplant outcomes in the United States: A 25-year National Cohort Study

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Abstract

Background: Pediatric HLT remains uncommon in the United States and criteria for HLT are unclear. The objectives of this study were to review the indications, and outcomes of pediatric HLT.

Methods: Data from the Scientific Registry of Transplant Recipients heart and liver databases were used to identify 9245 pediatric isolated heart transplants (PHT), 14 134 pediatric isolated liver transplant (PLT), and 20 pediatric HLT (16 patients underwent sHLT [same organ donor] and four patients with a history of PHT followed by PLT [different organ donors]; age ≤21 years) between 1992 and 2017. Outcomes included patient survival, and 1-year rates of acute heart and liver rejection.

Results: The median age for pediatric HLT was 15.6 (IQR: 10.5, 17.9) years, and included 12 males (12/20 = 60%). In the HLT group, the most common indication for HT was CHD (12/20 = 60%), and the most common indication for liver transplant was cirrhosis (9/20 = 45%). The 1, 3, and 5 year actuarial survival rates in pediatric simultaneous HLT recipients (n = 16) were 93%, 93%, and 93%, respectively, and was similar to isolated PHT alone (88%, 81%, and 75.5%, respectively and isolated PLT alone (84%, 82%, and 80%), respectively. There was no heart or liver rejection reported in the HLT group versus 9.9% in heart and 10.6% in liver transplant-only groups, respectively.

Conclusion: Pediatric HLT is an uncommon but acceptable option for recipients with combined end-organ failure, with intermediate survival outcomes comparable to those of single-organ recipients.

KEYWORDS
heart transplant, liver transplant, heart-liver transplant

Abbreviations: CHD, congenital heart disease; ECMO, extracorporeal membrane oxygenator; eGFR, estimated glomerular filtration rate; HLT, heart-liver transplantation; HT, heart transplant; INR, international normalized ratio; PHT, pediatric heart transplant; sHLT, simultaneous heart-liver transplantation; SRTR, Scientific Registry of Transplant Recipients; UNOS, United Network for Organ Sharing; VAD, ventricular assist device.

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1 | INTRODUCTION

Hepatic dysfunction is a known complication among advanced heart failure patients awaiting heart transplantation.[1] The etiology for hepatic dysfunction in these patients is multifactorial and includes long-standing central venous congestion along with systemic hypoperfusion; these hemodynamic derangements can lead to variable degrees of hepatic dysfunction.[2,3] Liver dysfunction contributes to significant long-term morbidity and mortality in advanced heart failure patients and may necessitate consideration of combined HLT.[4-6] As clinicians, it can be difficult to know which patients have severe enough damage to their liver to warrant dual-organ transplant as opposed to HT alone.[7] HLT has become a promising option for select adult patients who have end-stage heart failure and cirrhosis, with comparable survival outcomes to those of isolated heart or liver only transplantation with 1- and 10-year survival rates of more than 80%, and 70%, respectively.[4-6]

With the evolution of surgical techniques, an increasing number of patients with complex CHD who have undergone palliative procedures are now surviving into adulthood.[8,9] A significant proportion of these vulnerable patients eventually develop advanced heart failure necessitating a HT as the only survival strategy. The increased central venous pressures associated with many of these congenital cardiac pathologies can significantly compromise hepatic function and result in bridging fibrosis and cirrhosis.[8-11] Only a few pediatric transplant centers are currently performing combined HLT to treat dual end-organ failure and descriptions of pediatric HLT have, therefore, been limited to case reports and a few single-institution case series.[12-14] Given the limited published experience in pediatrics, the criteria for pediatric HLT are unclear. While it is still a rare pediatric procedure,[12-14] adult HLT frequency is on the rise.[4-6,15,16] Outcome data in dual-organ transplant recipients are needed to define the optimal utilization of scarce donor resources. We, therefore, performed this national cohort study to review the indications, and outcomes of pediatric HLT.

2 | MATERIALS AND METHODS

2.1 | Study population

The SRTR is a government-sponsored registry collecting data on all solid organ transplant recipients and donors in the United States. The SRTR maintains separate registries for heart and liver transplants.[17] Data from the SRTR were used to identify pediatric (age ≤21 years) heart alone, pediatric liver alone, and pediatric HLT recipients between January 1, 1992, and December 31, 2017. Demographic and transplant-specific data were collected for all pediatric patients undergoing isolated heart transplantation or HLT during this time period. Additionally, data were collected on outcomes following transplantation including patient survival, episodes of acute transplant rejection, death, and cause of death. Acute cardiac and liver rejection rates were determined based on reported cases of acute rejection on SRTR/UNOS follow-up forms or the use of antilymphocyte therapy (excluding induction therapy) within the first year post-transplant. This study was performed in accordance with the regulations of the institutional review board of Texas Children's Hospital, Baylor College of Medicine.

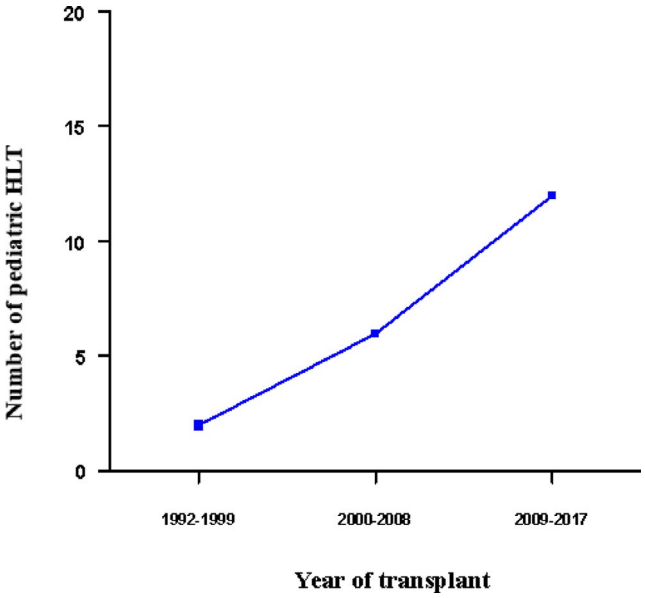

FIGURE 1 Pediatric HLT cases by year

2.2 | Statistical analysis

We separated HLT patients into two categories, (1) sHLT (n = 16) and (2) non-sHLT (n = 4). Organ recipient and donor characteristics are described using median ± interquartile range or frequencies as appropriate. Patient and graft survival in sHLT recipients (sHLT, n = 16) were estimated using the Kaplan–Meier product-limit method, and comparisons between groups were made using the log-rank test. All p-values were 2-tailed and a p-value at or below.05 was considered statistically significant. All analyses were performed using SAS Statistical Software (version 9.1, Cary, NC).

3 | RESULTS

3.1 | Demographics

Between January 1992 and December 2017, a total of 20 pediatric HLT were performed in the United States at 10 transplant centers. Of the 20 HLT, 16/20 (80%) patients underwent sHLT [same organ donor] and 4/20 (20%) patients had a history of pediatric HT followed by liver transplant (non-sHLT, different organ donors). During the same period, 9245 pediatric isolated heart transplants (PHT), 14134 pediatric isolated liver transplant (PLT) were performed. The frequency of HLT according to the era of transplant is shown in Figure 1. More pediatric HLT were performed in the later years

of cohorts. The demographic characteristics of patients undergoing HLT (n = 20) and single-organ PHT are shown in Table 1. The demographic characteristics of patients undergoing sHLT (n = 16) compared to non-sHLT (n = 4) are shown in Table 2.

3.2 | Demographics and indications for transplantation

The median age for pediatric patients undergoing HLT was 15.6 (10.5, 17.9) years, and included 12 males (12/20 = 60%). In the HLT group, the most common indication for HT was CHD (12/20 = 60%), followed by coronary artery vasculopathy (3/20 = 15%). The most common indication for liver transplant was cirrhosis (9/20 = 45%) with granulomatous diseases including sarcoidosis, histiocytosis, or cryptogenic listed as etiologies for cirrhosis. The other common indications for a liver transplant were familial homozygous hypocholesteremia (3/20 = 15%), extrahepatic biliary atresia (1/20 = 5%), and cirrhosis related hepatocellular carcinoma (1/20 = 5%). Six patients did not have an etiology for their liver failure listed (6/20 = 30%).

3.3 | Immunosuppression

In patients who underwent HLT and survived at least 6 months from transplantation (n = 16) the majority (75%) were on a combination regimen of at least two immunosuppressive agents. The most commonly used immunosuppressive agents were tacrolimus (62%), corticosteroids (50%), and cyclosporine (25%).

3.4 | Patient survival

Recipients of pediatric sHLT had a similar 5-year adjusted risk of death compared to single-organ PHT (p = .18, Figure 2). The 1-, 3-, and 5-year actuarial survival rates in pediatric sHLT recipients were 93%, 93%, and 93%, respectively, and were similar to isolated PHT alone (88%, 81%, and 75.5%) and isolated PLT alone (84%, 82%, and 80%), respectively. Of the 20 HLT patients, 4 (20%) died after a median of 30 days (range 4 days to 4.5 months). Causes of death in HLT group include stroke (n = 1), fungal sepsis (n = 1), and multiple-organ failure (n = 2). Fifteen of 16 sHLT patients were alive at time of last follow-up compared with only one of four patients undergoing non-sHLT. Thus far there has been only one reported case of simultaneous HLT performed in an infant for CHD with extrahepatic biliary atresia in the transplant registry. This sHLT was performed at 5 months of age in the year 1997 and the infant died after 29 days from stroke. This was the only reported death in the sHLT group (1/16). For those who underwent non-sHLT (n = 4) the median time interval to needing a liver transplant was 4.8 years (range 8 months to 8 years). Ten of the 16 patients who underwent sHLT have been followed up for more than 5 years.

3.5 | Complications

There were no episodes of heart or liver transplant rejection reported in the pediatric HLT group within the first year following HLT. In comparison, rates of acute rejection within the first year following single-organ heart and single-organ liver transplantation were 9.9% and 10.6%, respectively. Additional post-transplant complications in the HLT cohort included one case of cytomegalovirus infection. There were no incidences of Epstein–Barr virus infection or post-transplant lymphoproliferative disease documented in the HLT cohort.

4 | DISCUSSION

Our study provides a comprehensive review of pediatric HLT performed in the United States from 1992 to 2017. Since the first reported successful HLT in the mid-1980s,[14] this form of dual-organ transplantation has gained acceptance as a therapy for patients with concomitant end-stage dual-organ failure. However, as shown in our 25-year national cohort study, pediatric HLT remains a rare event, with only 20 having been performed from 1992 to 2017. The UNOS/

TABLE 1 Baseline characteristics among 20 pediatric HLT (16 patients who underwent sHLT [same organ donor] +4 patients with history of prior single-organ HT followed by a single-organ liver transplant [different organ donors]) in SRTR between 1992 and 2017

Variable	HLT (n = 20)	PHT (n = 9245)
Age in year at HT	15.6 (10.5, 17.9)	7.8 (0.9, 15.3)
Height (cm)	160 (141, 169)	120 (71.0, 160)
Weight (kg)	56 (35.4, 60.7)	22.3 (8.0, 52.0)
	n (%)	n (%)
Gender, male	12 (60)	5212 (56.4)
Race		
White	10 (50)	5377 (58.2)
Black	2 (10)	1883 (20.4)

Values expressed as median (IQR) or n (%) as appropriate.

TABLE 2 Baseline characteristics among simultaneous heart–liver transplant (sHLT, same organ donor) and non-simultaneous heart–liver HT

Variable	Simultaneous HLT (*n* = 16)	Non simultaneous HLT (*n* = 4)
Age in year at HT	15.6 (13.4, 18.9)	11.4 (5.2, 17.7)
Height (cm)	162 (154, 169)	130 (94, 165)
Weight (kg)	56 (44.4, 59.8)	42 (15, 68)
	n (%)	*n* (%)
Gender, male	10 (62.5)	2 (50%)
Race African American	1 (6.3)	1 (25%)
Diagnosis, *CHD*	12 (75)	0
VAD	0	0
ECMO	0	0
Transplant year ≥2005	15 (93.8)	1 (25)
eGFR ≤35 ml/min/1.73 m^2	1 (6.3)	1 (25)
Ischemic time (>4 h)	9 (56.3)	0

Values expressed as median (IQR) or *n* (%) as appropriate.

eGFR - there were no reported patients on dialysis in the dataset.

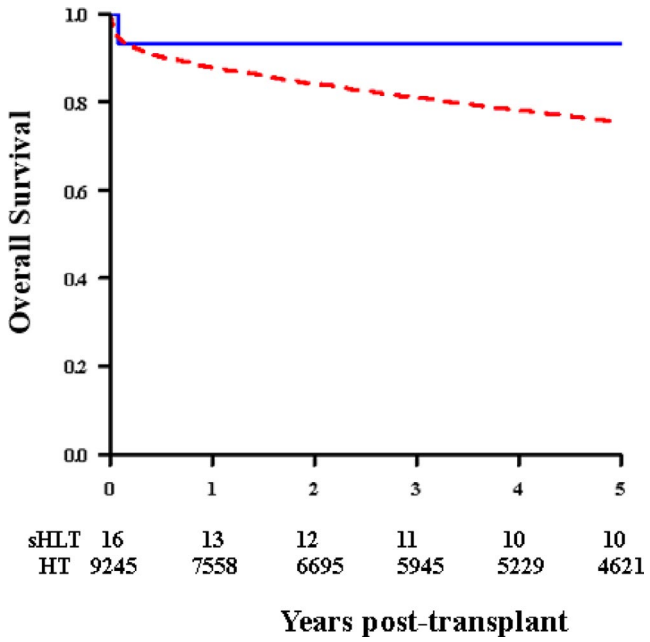

FIGURE 2 Patient survival for sHLT versus HT alone. The 1, 3, and 5 year actuarial survival rates in pediatric sHLT recipients was 93%, 93%, and 93%, respectively, and was similar to isolated PHT alone (88%, 81%, and 75.5%, respectively (p = .18)

Organ Procurement Transplant Network has reported 258 patients (246 adults, and 12 pediatric [age < 16]) as having undergone HLT s performed in the United States to date (between 1988 and 2018).[16] The procedure requires a high degree of expertise; therefore, pediatric institutional experience with dual HLT is limited. Given its rarity, the best utilization of this therapeutic option remains to be defined, as do the outcomes following this procedure. Our study represents the largest reported cohort of pediatric heart and liver transplant recipients, and several of the insights gained from this study may help shed light on these unanswered questions.

CHD and associated cirrhosis were observed to be the most common indications for pediatric HLT in our study, with 12 of 20 (60%) of patients receiving HLT reported as having a cardiac etiology for their heart and liver failure. As survival after palliation of complex CHD improves, increasing numbers of young adults are exhibiting the effects of longstanding abnormal hemodynamics on other organs, particularly the liver. This is reflected in the median age of our HLT population with CHD, approaching 18 years of age. Hepatic abnormalities and eventual liver dysfunction are increasingly being recognized as important complications developing late after Fontan palliation.[18-21] Previous single-center experiences in HLT from Vallabhajosvula et al[19] and Hollander et al[13] reflect this, with four of 10 and three of three patients in each study, respectively, undergoing HLT due to failing Fontan physiology. While the most appropriate indications for HLT in the pediatric population deserve further discussion, this study and others suggest that it can be a viable option to address both the heart and liver dysfunction resulting from longstanding effects of palliated CHD. As described in our results, only one out of these 12 patients (1/12 = 8.3%) with CHD who underwent HLT died during the study period.

While patients with dual-organ dysfunction heading into transplant may be perceived as having a higher operative risk and decreased likelihood of long-term survival compared to single-organ transplant candidates, we found that the graft survival after sHLT is about 93% at one year and 5 years, similar to the published survival rates in isolated liver or heart transplantation.[13,22-24] An adult national cohort study using the UNOS database reported 41 patients who underwent combined HLT and demonstrated 1- and 5-year survival rates of 84.8% and 75.6%, respectively[22]; this was comparable to rates of survival after adult single-organ liver and single-organ

heart transplantation.[6] In agreement with our study, previous single-center pediatric publications have also reported similar short and intermediate-term survival outcomes after combined HLT.[13,19] Ten of the 16 patients who underwent sHLT have been followed up for more than 5 years, suggesting the possibility of a promising intermediate to long-term outcome after this procedure. Defining outcomes after HLT will remain critical to determining the appropriateness of this therapy, especially since considering this therapy utilizes two organs for one patient, further reducing an already limited pediatric organ donation pool.

Our study illustrated a potential beneficial immunologic effect of dual-organ transplantation, with no reported episodes of acute heart or liver graft rejection within the first year post-transplant. This is concordant with previously published reports: Cannon and colleagues reported that adult combined HLT recipients with greater than 1-year survival had a lower incidence of acute liver rejection than those undergoing liver transplant alone (5.2% vs. 12.2%, $p = .06$).[4] Similarly the incidence of acute cardiac rejection was also lower in the group undergoing combined HLT than in the cardiac transplant alone group (8.9% vs. 23.9%, $p = .002$).[4] Other authors have reported that combined HLT recipients can be maintained on much lower doses of immunosuppression than their isolated HT patients, which suggests that the liver does provide some immune-protective effect.[4,22,25-27] Given the small numbers in our and other studies, this potential immunologic benefit of dual-organ transplantation warrants further study.

With the advancement of surgical techniques and improved perioperative management, an increasing number of patients with palliated complex CHD are now surviving into adulthood. Both children and adults are surviving to develop heart and liver dysfunction or failure. It is important to have as much information as possible to make complex decisions in regards to the advisability of dual-organ transplantation.[28,29] Currently, data are limited, and therefore, there are no published guidelines regarding evaluation or eligibility for dual HLT. While practices currently vary, this study demonstrates that there is a reasonable expectation for good intermediate-term outcomes in children and teenagers who undergo HLT.

4.1 | Limitations

Our study was a retrospective review of a national transplant database with limitations inherent to this study design. Given the small number of patients in the HLT group, this study may not have been adequately powered to detect a difference. Only variables already captured could be studied. Incomplete or missing data for certain variables were noted. There was limited information about immunosuppressive regimens, induction, and maintenance protocols. Based on center practice, immunosuppression regimens after dual-organ transplantations may vary. There is a possibility that centers provide a more intense immunosuppressive regimen to the HLT recipients compared to isolated PHT. It is unknown whether more aggressive therapy may have favorably biased survival toward the dual-organ recipients. We investigated graft rejection within the first year. Rejection rates beyond the first year are not available in the registry. Therefore, we cannot provide any information about whether or not the allograft rejection rate was accelerated in either group beyond the first year. The database that does not provide information on surgical technique used for HLT. Furthermore, given the non-granular nature of data collection in the transplant registry, we may have failed to detect subclinical episodes of heart or liver allograft rejection that were not captured in the database. Additionally, the database did not provide information on the type of surgical technique used for HLT.

5 | CONCLUSION

This study has shown that pediatric HLT is a viable option for recipients with combined end-stage heart and liver dysfunction, with intermediate survival outcomes comparable to those of single-organ recipients with no treated heart or liver rejection reported in the first year. It is important to develop evidence-based guidelines for dual or multiorgan allocation to be able to rationally utilize these scarce donor resources. HLT will increasingly be utilized given the aging population of palliated CHD patients and warrants consideration as a viable treatment option in patients with dual-organ failure.

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The data reported here have been supplied by the Scientific Registry of Transplant Recipients (SRTR) registry. The interpretation and reporting of these data are the responsibility of the author(s).

CONFLICT OF INTEREST

None.

AUTHOR CONTRIBUTION

Dr. Choudhry, and Dr. Denfield conceptualized and designed the study, drafted the initial manuscript, critically reviewed, revised, and approved the final manuscript as submitted. Dr. Dreyer designed the study, critically reviewed, revised, and approved the final manuscript as submitted. Drs. Hope, Spinner, Tunuguntla, Cabrera, and Price, critically reviewed and revised the manuscript. Dr. Wang carried out the statistical analyses, and critically reviewed and revised the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

DATA AVAILABILITY STATEMENT

The data reported here have been supplied by the Scientific Registry of Transplant Recipients (SRTR) registry. The interpretation and reporting of these data are the responsibility of the author(s).

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