Pediatric urgent heart transplantation with age or weight mismatched donors: Reducing waiting time by enlarging donor criteria

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Abstract
Background: Despite considerable progress in heart transplantation, pediatric waiting list mortality is still high, and often patients do not have enough time to wait. We hypothesized that extending the donor criteria regarding age and weight mismatch does not significantly affect the early follow-up.

Methods: We retrospectively analyzed our pediatric heart transplantation patients operated on from 2014 to 2020 for high (>3.0) or low (<0.6) donor-recipient weight ratio (DRWR) or chronological age mismatches (donor organ >5 years older than recipient age). This patient cohort constituted “mismatched heart transplantations” (mHTX). We compared mHTX preoperative status, postoperative course, 1-year survival, and early clinical follow-up to standard pediatric heart transplantations (sHTX).

Results: We performed 20 pediatric heart transplantations—10 mHTX and 10 sHTX. The minimum DRWR was 0.44, the maximum was 5.60, and the maximum age mismatch was 42.6 years. Median days in the intensive care unit ($p = .436$) and time-to-first-rejection episode ($p = .925$) were comparable. Nine patients in each group were alive after 1 year, two patients were operated within 1 year of follow-up. One mHTX patient developed cardiac allograft vasculopathy after 15 months and died 648 days after transplantation ($p = .237$). All other patients were alive at the end of follow-up and in good clinical conditions (median follow-up for mHTX was 732.5 days, 1149.5 days for sHTX).

Conclusion: Postoperative course and early follow-up after mHTX were comparable to sHTX. In urgent clinical situations, extended donor criteria may be considered an additional option for pediatric heart transplantation.
1 | INTRODUCTION

Pediatric heart transplantation is the treatment option of choice for end-stage heart failure, but waiting list mortality is still between 12% and 30%. The main limitation is the shortage of available donor hearts and their acceptability for transplantation. The rate of organ refusal can reach 40%, mostly attributed to poor donor quality.

To enlarge the donor pool, the impact of donor characteristics on pediatric heart transplant outcomes has been extensively debated. There is no common agreement on the influence of weight mismatch, donor age, ABO compatibility, donor comorbidities, or infections on heart transplant outcomes in children. Recently, the International Society of Heart and Lung Transplantation (ISHLT) published a consensus statement summarizing the scientific evidence on pediatric heart transplantation donor organ acceptability.

In our study, we focused on the ISHLT consensus statement recommendations that suggest donor organs should be less than 5 years older than the recipient and donor-recipient weight ratio (DRWR) should range between 0.6 and 3.0. We hypothesized that violating these specific age and weight match recommendations may not influence early outcomes in selected clinical situations while enabling more timely pediatric heart transplants.

2 | METHODS

We retrospectively collected and analyzed all patients under 18 years of age who underwent heart transplantation in our institution from January 2014 to December 2020. We considered the guidelines published by the ISHLT and focused on the weight and age indications.

Mismatched heart transplantation (mHTX) criteria were DRWR < 0.6 or >3.0 and/or patients who received a donor organ >5 years older than their chronological age, especially if the donor was >25 years of age. All the other pediatric patients followed ISHLT donor criteria were considered the standard heart transplantation (sHTX) control group.

To accept donor hearts for transplantation, we first considered standard hemodynamic parameters, in particular the calculated cardiac output request from the patients (according to weight) and the calculated cardiac output of the donor. In addition, we compared sizes of donor and recipient hearts, according to available radiologic imaging. Throughout the study, the medical and surgical treatment remained unchanged.

We collected standard donor parameters and clinical pre-transplantation data of recipients, as well as postoperative course, survival rate, complications, and early clinical follow-up. We considered the patients’ 1-year survival as the primary endpoint. Secondary endpoints included postoperative complications and clinical follow-ups, namely, the time in intensive care unit, need for open chest, New York Health Association (NYHA) class at last follow-up, rejection episode, incidence of posttransplant lymphoproliferative disease (PTLD), and cardiac allograft vasculopathy (CAV).

Depending on the distribution of the values considered, data were expressed as absolute numbers, averages, and standard deviation, or medians and interquartile ranges. We used two-tailed t-tests or Mann-Whitney U tests for comparisons, as appropriate. Time-related endpoints were analyzed by Kaplan-Meier and compared by log-rank tests. A Cox regression analysis including multiple variables was considered desirable, but not appropriate due to the small numbers of patients and events.

This study was approved by the local institutional review board and all parents of the patients provided written informed consent. This study complies with the ISHLT ethical declaration.

3 | RESULTS

3.1 | Clinical characteristics

Twenty patients under 18 years of age underwent heart transplantation in our center during the study period. Ten patients were transplanted with a significant age and/or weight mismatch (mHTX group) and 10 patients received organs according to standard criteria (sHTX group).

The median recipient age in mHTX patients was 13.5 years (3.1; 15.5) and 1.7 years in sHTX (0.8; 9.7). The median DRWR in the sHTX group was 1.2 (0.9; 1.4), while it was 1.4 (1.2; 3.0) among the mismatch patients. The minimum DRWR in the mHTX group was 0.44 and maximum was 5.60.

The median age mismatch in sHTX group was 0.3 years (-0.5; 1.1) and 24.2 years in the mHTX group (12.8; 37.4), with a maximum of 42.6 years. Specific age and weight data for mHTX patients and donors are shown in Table 1.

Five mHTX patients had cardiomyopathy (50%), four had a congenital heart defect (CHD, 40%), and one (10%) had myocarditis. Four sHTX patients (40%) had cardiomyopathy, four had CHD (40%), and two (20%) had myocarditis.

Three sHTX patients required extracorporeal membrane oxygenation (ECMO) and then switched to a ventricular assisted device (VAD) as bridge to transplant, and two patients needed only VAD support. In the mHTX group, seven patients required support devices: four patients needed ECMO and were not VAD candidates, one patient got VAD support, and two patients needed ECMO and then switched to VAD support.

The median waiting list time for mHTX and sHTX patients was 51.0 days (7.5; 164.0) and 177.0 days (46.2; 843.2; p = .123), respectively (Table 2).
3.2 | Postoperative course and complications

Postoperative data for the mHTX and sHTX groups are detailed in Table 3. The median ventilation time was 67.7 h in the mHTX group and 70.0 h in the sHTX group (p = .515) and median ICU stay was 10.5 days for mHTX patients and 19.5 days for sHTX patients (p = .436). No patient needed a delayed sternum closure despite the size mismatch, but four patients after mHTX and three after sHTX needed posttransplant dialysis therapy (p = .500). Two mHTX patients needed postoperative ECMO support due to low cardiac output; one received the heart from a 60-year-old donor and the second had a DRWR of 0.44. Four mHTX patients underwent a second operation during the same hospitalization: two for secondary pacemaker implantation and two for a suspected bleeding. Three of these patients had an age mismatch and one had a DRWR of 0.44.

Three mHTX patients (two age mismatched patients and the patient that got a smaller heart) had postoperative infections within 30 days after transplantation. Three sHTX patients had postoperative infections (p = .686) (Table 3).

One mHTX and one sHTX patient needed a late secondary implantation of a pacemaker, 18 and 31 months after transplantation, because of atrioventricular block Grade III and sick sinus syndrome, respectively.

3.3 | Survival, follow-up, and late complications

Survival data for the mHTX and sHTX groups are detailed in Table 3. Nine mHTX patients and nine sHTX patients were alive 1 year after survival. One mHTX and one sHTX patient were operated on within 1 year of follow-up (294 and 52 days, respectively). Nine mHTX patients survived to a median follow-up of 732.5 days (373.0; 1385.0) and 10 sHTX patients to a median follow-up of 1149.5 days (572.5; 1855.0) (Figure 1). All 19 patients were in good clinical conditions (NYHA I) at the end of the follow-up period. One mHTX patient who received a heart from a 60-year-old donor (Patient 6, Table 1) developed severe cardiac allograft vasculopathy (CAV) 15 months posttransplantation and died at Day 648 (Table 3) in a rehabilitation clinic because of ventricular fibrillation of unclear cause (p = .237).

Six mHTX and five sHTX patients presented with at least one rejection episode during follow-up (p = .925). All of them were successfully treated with prednisolone therapy but two sHTX patients had a successfully treated second rejection episode. Posttransplant lymphoproliferative disease (PTLD) was observed three times in both patient groups (Table 3).

3.4 | mHTX subgroup characteristics

The mHTX group was also analyzed as subgroups: age mismatched (nine patients); weight mismatched (one patient); and age and weight mismatched (three patients). Pre-transplantation, postoperative, and follow-up characteristics of the mHTX subgroups are detailed in Tables S1 and S2.

Among the patients who received a heart transplantation following mismatched donor criteria, nine patients had a median age mismatch of 27.8 (range 9.4; 42.6) and three of them had a combined weight (DRWR 3.0, 3.03, 5.6) and age mismatch. A 2.4-year-old patient had a relevant low weight mismatch (DRWR 0.44) and received a heart from a 4-month-old infant (Patient 3, Table 1).

The median ventilation time of age mismatched patients was 39 and 96 h among patients with combined age and weight mismatch. The patient that received a small heart needed to be ventilated for 29 days and stayed in the ICU for 163 days. The age mismatched patients had a median ICU stay of 10 days while the patients that obtained bigger hearts had a median ICU stay of 19 days.

### Table 1 | Age and weight parameters for mHTX patients and donors

| Recipient age (years) | Recipient weight at transplant (kg) | Donor age (years) | Donor weight (kg) | DRWR | Age mismatch (years) |
|----------------------|--------------------------------------|-------------------|------------------|------|---------------------|
| Patient 1            | 1.6                                  | 11.6              | 39               | 65   | 5.60                | 37.4 |
| Patient 2            | 9.2                                  | 30.0              | 22               | 90   | 3.00                | 12.8 |
| Patient 3            | 2.4                                  | 11.3              | 0.33             | 5    | 0.44                | -2.4 |
| Patient 4            | 13.6                                 | 66.0              | 27               | 90   | 1.36                | 13.4 |
| Patient 5            | 15.8                                 | 58.9              | 49               | 70   | 1.19                | 33.2 |
| Patient 6            | 17.4                                 | 44.4              | 60               | 52   | 1.17                | 42.6 |
| Patient 7            | 15.5                                 | 47                | 36               | 69   | 1.47                | 20.4 |
| Patient 8            | 3.1                                  | 15.5              | 31               | 47   | 3.03                | 27.8 |
| Patient 9            | 13.4                                 | 58.6              | 55               | 70   | 1.20                | 41.6 |
| Patient 10           | 13.6                                 | 36                | 23               | 56   | 1.56                | 9.4  |

Abbreviation: DRWR, donor-recipient weight ratio; mHTX, mismatched heart transplantations.
The patient who received a smaller heart and five patients with age mismatch (one of whom had a combined age and weight mismatch) had a rejection episode.

4 | DISCUSSION

While the effectiveness of heart transplantation as a treatment for end-stage heart failure is undebated, the indications for organ acceptability remain ill-defined. The main limitation is the low availability of suitable organs and the related waiting list mortality (between 12% and 30%).\(^1\)\(^-\)\(^3\) There have been increasing efforts to expand the donor pool by extending donor criteria, thereby allowing a reduction of the waiting time. Current indications in adult heart transplantation consider an ideal DRWR to be between 0.8 and 1.2, but there are several studies on the impact of greater size mismatch, and it seems that is not associated with a higher mortality.\(^1\)\(^1\)\(^-\)\(^13\)

In the pediatric transplant population, these constraints have always been handled less rigidly as organ size discrepancies between children may have less impact than in adults and waiting times for ideal matches could be excessive due to limited pediatric donor availability. The consequences of enlarging the matching criteria have been largely debated, mostly about early and late complications. The ISHLT reported in 2017 that the greatest risk of death is in the first-year post heart transplant, and those patients who survived the first year had a median survival of more than 15 years.\(^1\)\(^4\)\(^,\)\(^15\) In 2003 Razzouk et al.\(^1\)\(^6\) analyzed the effect of oversized pediatric heart transplantation and concluded that the common morbidities of cardiac transplantation and long-term survival of children with complex congenital heart disease are not adversely influenced by the use of oversized cardiac allografts. Tang et al.\(^1\)\(^6\) focused on the issue of low DRWR and showed that despite smaller organs, patients did not have longer inotropic support or higher short-term mortality. In addition, short-term morbidity and long-term survival did not differ from standard donors.

Another question about heart allocation is the effect of older donor age on the survival after heart transplantation. In 1999, Chin and colleagues reported a significantly worse outcome with the use of advanced-age donor hearts, especially in adolescent patients and suggested to not use donors >40 years of age.\(^1\)\(^7\) Recently, Westbrook and colleagues suggested to prefer donors not more than 5 years older than the chronological recipient age to avoid poor outcomes including frequent onset of CAV.\(^6\)\(^,\)\(^15\)

In 2020, Conway and colleagues’ meta-analysis of the characteristics of the ideal donor in pediatric heart transplantation, they found that the DRWR should be between 0.7 and 3 and that donor age should be <50 years old.\(^1\) That same year, the ISHLT published a consensus statement describing donor organ acceptability criteria for pediatric heart transplantation. The ISLHT proposed to aim for a DRWR between 0.6 and 3.0 and, especially in adolescents, the organ should not come from a donor >5 years older, especially if the donor is >25 years of age.\(^1\)\(^0\)

| Parameters                          | mHTX       | sHTX       | \(p\) value |
|-------------------------------------|------------|------------|-------------|
| Number of patients                  | 10         | 10         |             |
| Median patient age (years)          | 13.5 (3.1; 15.5) | 1.7 (0.8; 9.7) | .035        |
| Median DRWR                         | 1.4 (1.2; 3.0) | 1.2 (0.9; 1.4) | .218        |
| Median donor age (years)            | 33.5 (22.7; 50.5) | 2.0 (0.9; 10.7) | .001        |
| Median age mismatch (years)         | 24.2 (12.8; 37.4) | 0.3 (−0.5; 1.1) | .001        |
| Male                                | 5          | 4          | .500        |
| Sex mismatch                        | 5          | 5          | 1.000       |
| Median patient weight (kg)          | 40.2 (15.5; 58.6) | 9.9 (30.6; 7.1) | .015        |

Pretransplantation intervention

| Pretransplantation intervention     | mHTX | sHTX | \(p\) value |
|-------------------------------------|------|------|-------------|
| Cardiomyopathy                      | 5    | 4    |             |
| CHD                                 | 4    | 4    |             |
| Myocarditis                         | 1    | 2    |             |
| Pretransplantation ECMO             | 8    | 10   | .237        |
| Pretransplantation VAD              | 1    | 2    | .500        |
| Pretransplantation ECMO and VAD     | 2    | 3    | .500        |
| Median time on waiting list (days)  | 51.0 (7.5; 164.0) | 177.0 (46.2; 843.2) | .123        |

Note: Data presented as median (interquartile range) and absolute number.

Abbreviations: CHD, congenital heart disease; DRWR, donor recipient weight ratio; ECMO, extracorporeal membrane oxygenation; mHTX, mismatched heart transplantation; sHTX, standard heart transplantation; VAD, ventricular assisted device.
Weight ratio as matching criteria is also recently debated. Recipient bodyweight not always mirrors cardiac size and is often influenced by the symptoms of the pathology that brings the patient to transplant: fluid retention, failure to thrive, cardiomegaly, cachexia, or obesity can affect body weight without corresponding heart size modification.\textsuperscript{7,18–20} To overcome this limitation, Ploutz et al.\textsuperscript{7} suggested to switch to a volume-based size matching strategy by calculating the total cardiac volume (TCV) by magnetic resonance imaging or echocardiography.\textsuperscript{7,21} Alternatively, Plasencia et al. developed a prediction model for TCV and suggested performing a “virtual implantation” through imaging before heart transplantation.\textsuperscript{20} In our experience, we compare the size of donor and recipient hearts through available imaging and hemodynamic parameters, in particular cardiac output request from the patient and the cardiac output of the donor.

Several patients of our center were considered at high risk of waiting list mortality and we, therefore, performed 10 transplantations where donor criteria were reasonably—or in some cases considerably—extended. sHTX and mHTX patients had comparable immediate postoperative courses, 1-year survival, and incidence of complications. Despite the age mismatch, only three of these patients had even a weight mismatch but that can be explained because adolescents have often already reached adult range weight. The short-term follow-up showed no significant differences between patients with standard and mismatched donor criteria but there was one death after 648 days among mHTX patients. All other patients are at the end of the study alive, asymptomatic, and hemodynamically stable ($p = .237$).

While average pediatric waiting list mortality is between 12\% and 30\%,\textsuperscript{1,2} the adoption of these extended donor criteria allowed us to reduce the risk of death while waiting for transplantation to 9.09\%, and in the last 6 years, only two patients died while waiting for transplantation. Therefore overall, there were two deaths for 6776 patient waiting days, equating to 10.8 deaths per 100 waiting-list years, which is remarkably decreased compared to the 32 deaths per 100 waiting-list years between 2011 and 2015 of the Australian experience.\textsuperscript{22} This is important, since even in the last 15 years, in the age of availability of pediatric ventricular-assist devices (VADs), waiting list mortality remains relevant.\textsuperscript{22}

| Parameters                                      | mHTX ($n = 10$) | sHTX ($n = 10$) | $p$ value |
|-------------------------------------------------|-----------------|-----------------|----------|
| Median ventilation time (h)                     | 67.7 (21.5; 144.0) | 70.0 (30.7; 180.4) | .515     |
| Median days in the ICU                          | 10.5 (7.0; 25.5)  | 19.5 (8.5; 38.0)  | .436     |
| Open sternum                                    | 0               | 0               |          |
| Postoperative dialysis                          | 4               | 3               | .500     |
| Reoperation                                     | 4               | 0               | .143     |
| 2 suspected bleedings                            |                 |                 |          |
| Postoperative infection (<30 days)              | 3               | 3               | .686     |
| Postoperative pacemaker implantation            | 2               | 0               | .237     |
| Postoperative ECMO                              | 2               | 0               | .237     |
| 1-year survival                                 | 9               | 9               | 1.000    |
| Survival at end of follow-up                    | 9               | 10              | .237     |
| Median follow-up (days)                         | 732.5 (373.0; 1385.0) | 1149.5 (572.5; 1855.0) | .247     |
| NYHA at last follow-up                          | 1               | 1               |          |
| First rejection episode                         | 6               | 5               | .925     |
| Second rejection episode                        | 0               | 2               | .241     |
| PTLD                                            | 3               | 3               | .427     |
| CAV                                             | 1               | 0               | .180     |

Note: Data presented as median (interquartile range) and absolute number.

Abbreviations: CAV, cardiac allograft vasculopathy; ECMO, extracorporeal membrane oxygenation; ICD, implantable cardioverter-defibrillator; ICU, intensive care unit; mHTX, mismatched heart transplantation; NYHA, New York Heart Association classification; PTLD, posttransplant lymphoproliferative disease; sHTX, standard heart transplantation.
Various attempts have been made to define the parameters that increase the risk of death on the heart transplantation waiting list: higher serum creatinine or renal replacement therapy; ineligibility for mechanical circulatory support; need for ECMO or ventilator support; CHD as the main diagnosis; ABO blood group 0; and smaller body size were all considered of importance.\textsuperscript{1,22,23}

Risk factors that are considered in our center’s multidisciplinary consultations include hospitalization, ECMO therapy in a non-VAD candidate, the need for vasopressor/inotrope therapy, state of low cardiac output, and the presence of arrhythmias. The death of the patient who received a heart from a 60-year-old donor, agrees with the findings of Westbrook and who found worse long-term outcomes for greater age mismatched transplants.\textsuperscript{6} There is a significantly worse outcome with the use of advanced-age donor hearts and we should therefore properly adapt follow-up care.

We report encouraging 1-year survival results in our mHTX patients. Therefore, according to our results, in properly selected situations it is possible to perform heart transplantation with extended age and weight donor criteria to reduce waiting list mortality.

5 | LIMITATIONS

The ongoing discussion about the risks or benefits of extended donor criteria in pediatric heart transplantation will remain complex due to the variety of patients and therapeutic options. Our retrospective evaluation of 20 patients is limited by the low number of cases and not yet available long-term outcomes. Unfortunately, due to the low number of patients it is not possible to perform a valid statistical analysis of the subgroups, which are only described. As always, multi-centered data with long-term follow-up in larger patient cohorts would be necessary to reconfirm our findings. Yet, our data still indicates that heart transplant decisions outside the 2020 ISHLT consensus pediatric matching recommendations might be beneficial for individual patients when the risk of death waiting for a transplantation is high.

6 | CONCLUSION

We observe that midterm outcomes of our 20 pediatric heart transplantations patients with either extended mismatch or standard donor/recipient age or weight ratios are similar. Therefore, in urgent situations it remains justified to consider extended donor criteria outside the 2020 ISHLT consensus statement to reduce the waiting time and to give a better chance to pediatric heart transplant candidates that cannot wait longer for a better donor age or weight match.

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CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.
AUTHOR CONTRIBUTIONS
Murat Avsar, Elena Petenà: conception and design; data collection; data analysis and interpretation; drafting of the manuscript; final approval; agreement to be accountable for all aspects of the work. The authors contributed equally and therefore share first authorship. Fabio Ius: conception and design; data collection and interpretation; manuscript revision; final approval; agreement to be accountable for all aspects of the work. Dmitry Bobylev, Tomislav Cvitkovic, Valery Tsimashok: data collection; revision of the manuscript; final approval; agreement to be accountable for all aspects of the work. Gregor Warnecke: conception and design; data collection and interpretation; manuscript revision; final approval; agreement to be accountable for all aspects of the work. Dmitry Bobylev, Tomislav Cvitkovic, Valery Tsimashok: data collection; manuscript revision; final approval; agreement to be accountable for all aspects of the work. Philipp Beerbaum: conception and design; data collection; analysis and interpretation; manuscript revision; final approval; agreement to be accountable for all aspects of the work. Dietmar Böthig: conception and design; data collection, analysis and interpretation; manuscript revision; final approval; agreement to be accountable for all aspects of the work. Alexander Horke: conception and design; data collection and interpretation; manuscript revision; final approval; agreement to be accountable for all aspects of the work. Axel Haverich: conception and design; data collection and interpretation; manuscript revision; final approval; agreement to be accountable for all aspects of the work. Gregor Warnecke: conception and design; data collection and interpretation; manuscript revision; final approval; agreement to be accountable for all aspects of the work. Dmitry Bobylev, Tomislav Cvitkovic, Valery Tsimashok: data collection; final approval; agreement to be accountable for all aspects of the work. Philipp Beerbaum: conception and design; data collection; analysis and interpretation; manuscript revision; final approval; agreement to be accountable for all aspects of the work. Dietmar Böthig: conception and design; data collection; analysis and interpretation; manuscript revision; final approval; agreement to be accountable for all aspects of the work. Philipp Beerbaum: conception and design; data collection; analysis and interpretation; manuscript revision; final approval; agreement to be accountable for all aspects of the work. Dietmar Böthig: conception and design; data collection; analysis and interpretation; manuscript revision; final approval; agreement to be accountable for all aspects of the work. Philipp Beerbaum: conception and design; data collection; analysis and interpretation; manuscript revision; final approval; agreement to be accountable for all aspects of the work.

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SUPPORTING INFORMATION
Additional supporting information may be found in the online version of the article at the publisher’s website.

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