

FEATURED PAPERS

Impact of initial Norwood shunt type on young hypoplastic left heart syndrome patients listed for heart transplant: A multi-institutional study



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KEYWORDS:

pediatric cardiac transplantation; hypoplastic left heart syndrome; single ventricle

BACKGROUND: Pulmonary blood flow during Stage 1 (Norwood) palliation for hypoplastic left heart syndrome (HLHS) is achieved via modified Blalock–Taussig shunt (MBT) or right ventricle to pulmonary artery conduit (RVPA). Controversy exists regarding the differential impact of shunt type on outcome among those who require transplantation early in life. In this study we explored waitlist and post-transplant outcomes within this sub-population stratified by shunt type.

METHODS: Eligible patients were enrolled through the Pediatric Heart Transplant Study (PHTS) database. Patients included those listed for heart transplantation at 1 of 35 participating centers, all of whom were <6 years of age and with a diagnosis of HLHS (and variants) status post Stage 1 palliation with MBT or RVPA. Standard risk factors for death were analyzed using multivariable hazards modeling.

RESULTS: Between 2010 and 2013, 190 patients were identified. Compared with the RVPA group ($n = 111$), the MBT group ($n = 79$) was less likely to have undergone a Glenn palliation (41% vs 73%, $p < 0.001$), were younger at listing (median age 1.3 vs 1.8 years, $p = 0.05$), had lower median weight (7.9 vs 9.4 kg, $p = 0.02$), and were more likely to be mechanically ventilated at listing (35% vs 22%, $p = 0.04$). There were no significant differences in median waitlist time (1.7 vs 2.6 months, $p = 0.2$) or rate of transplantation (61% vs 60%, $p = 1.0$). Among waitlisted patients, 3-month survival was less for MBT compared with RVPA patients (74% vs 91%, $p = 0.02$). Patients who had not yet achieved Glenn palliation before listing had lower waitlist 3-month survival (76% vs 90%, $p = 0.02$). In MBT infants <1 year old, there was a trend toward improved survival in those with Glenn palliation compared to those without (100% vs 68%, $p = 0.08$). Early post-transplant mortality rates were similar between the RVPA and MBT groups ($p = 0.4$) with overall survival 84% at 1 year.

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CONCLUSIONS: Among HLHS patients, the need for transplant before Glenn palliation is associated with poorer waitlist survival. Waitlist survival is poorer in the MBT group, with this difference driven by pre-Glenn MBT infants. Post-transplant outcomes were unaffected by shunt type.

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Surgical palliation for hypoplastic left heart syndrome (HLHS) has evolved over the past decade with the popularization of the right ventricle pulmonary artery (RVPA) conduit modification of the Norwood procedure. Currently, this operation and the Norwood surgery with a modified Blalock–Taussig (MBT) shunt are the most commonly performed palliations for HLHS infants. The Single Ventricle Reconstruction (SVR) Trial explored survival differences between the RVPA and MBT groups and found a significant risk of mortality (32%) or need for cardiac transplantation (4%) by 3 years of age in the trial population, irrespective of shunt type.^{1,2}

Outcome differences after listing or transplantation according to initial Norwood shunt type have not been sufficiently explored. Since 2010, the Pediatric Heart Transplant Study (PHTS) has included a structured data field to collect shunt type. Analysis of PHTS data offers the advantages of a greater number of participating centers and enrolled subjects than the SVR Trial, unique data on sensitization rates, and outcomes data after transplantation. We hypothesized that there would be no differences in mortality after either waitlisting or transplantation between the RVPA and MBT groups.

Methods

Data collection

The PHTS database was queried for patients listed for transplantation between the Years 2010 and 2013 (before 2010, Norwood patients were coded without delineation of surgical subtype). Inclusion criteria consisted of: listing for heart transplantation within the PHTS; age <6 years at the time of listing; diagnosis of HLHS (and variants); and with Norwood Stage 1 palliation with MBT or RVPA conduit. Data were collected prospectively by local investigators at the 35 participating centers in the USA, Canada and the UK. Data were submitted to the central database at the time of listing, at the time of heart transplant (HT) and annually thereafter. The PHTS data warehouse and analysis center is located at the University of Alabama at Birmingham. Each center maintains institutional review board approval or obtains exemption according to institutional guidelines.

Exclusion criteria

Patients were excluded from analysis if ≥ 6 years at listing. This younger cohort most closely mirrors the modern era of Norwood palliation as in the SVR Trial. Also excluded were patients undergoing Norwood palliation with a diagnosis of congenital heart defect other than HLHS or related single ventricle variants. Exclusions included pulmonary atresia with intact ventricular septum, tetralogy of Fallot and balanced atrioventricular canal defects. HLHS patients undergoing heart transplant as a primary palliation were also excluded. Finally, patients undergoing the hybrid variant of the Norwood procedure were excluded, because

this group (a) included patients bridged to transplant as the intended pathway or (b) disproportionately represented the experience of a single center, which could introduce unwanted sample bias.

Statistical analysis

Data are reported as mean or median with standard deviation for continuous variables and frequency or percentage for categorical variables. Baseline intergroup characteristics were compared using the chi-square test for categorical values and the *t*-test for continuous variables. Median with interquartile range (IQR) is reported for the wait time from listing to heart transplant. Median waitlist time is calculated as the time from listing to transplant censored at death or removal from the waitlist. The primary outcome of interest was death after waitlisting, and a secondary analysis was performed for death after HT. Standard Kaplan–Meier non-parametric methods were used to determine survival after waitlist or HT, and Cox proportional hazards models identified independent risk factors for death. Kaplan–Meier survival curves were constructed with censoring at the time of transplant for waitlist survival curves. Statistical significance was achieved at $p \leq 0.05$. Hazard ratios (HRs) are presented with 95% confidence intervals (CIs). All statistical analyses were performed with SAS version 9 software (SAS Institute, Inc., Cary, NC).

Results

Patients' characteristics

Between 2010 and 2013, 190 patients met the inclusion criteria: 111 patients in the RVPA group and 79 in the MBT group. **Table 1** compares baseline characteristics of the groups. Compared with the RVPA group, the MBT group was less likely to have undergone Glenn (Stage 2) palliation (41% vs 72%, $p < 0.001$), were younger at listing (median age 1.3 vs 1.8 years, $p = 0.05$), had lower median weight (7.9 vs 9.4 kg, $p = 0.02$), and were more likely to be mechanically ventilated at listing (35% vs 22%, $p = 0.04$). There were no differences in listing status or sensitization rate. There was a trend toward greater extracorporeal membrane oxygenation (ECMO) use in the RVPA group (7% vs 1%, $p = 0.06$).

Waitlist survival

The median waitlist time was 1.7 months for the MBT group and 2.6 months for the RVPA group ($p = 0.2$). Competing outcomes after listing are depicted in **Figure 1a** and **b**. Multivariable hazard analysis revealed the following risk factors for death after listing: younger age (HR 1.03, 95% CI 1.02 to 1.04, $p = 0.02$) and Status 1A at listing (HR 3.81, 95% CI 1.43 to 10.21, $p = 0.008$). Having undergone MBT was a borderline risk factor (HR 1.87, 95% CI 0.94 to 3.71, $p = 0.07$). There was no difference in overall rate of

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