



## ORIGINAL CLINICAL SCIENCE

# Functional status of United States children supported with a left ventricular assist device at heart transplantation

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**KEYWORDS:**

pediatrics;  
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**BACKGROUND:** As survival with pediatric left ventricular assist devices (LVADs) has improved, decisions regarding the optimal support strategy may depend more on quality of life and functional status (FS) rather than mortality alone. Limited data are available regarding the FS of children supported with LVADs. We sought to compare the FS of children supported with LVADs vs vasoactive infusions to inform decision making around support strategies.

**METHODS:** Organ Procurement and Transplant Network data were used to identify all United States children aged between 1 and 21 years at heart transplant (HT) between 2006 and 2015 for dilated cardiomyopathy and supported with an LVAD or vasoactive infusions alone at HT. FS was measured using the 10-point Kamofsky and Lansky scale.

**RESULTS:** Of 701 children who met the inclusion criteria, 430 (61%) were supported with vasoactive infusions, and 271 (39%) were supported with an LVAD at HT. Children in the LVAD group had higher median FS scores at HT than children in the vasoactive infusion group (6 vs 5,  $p < 0.001$ ) but lower FS scores at listing (4 vs 6,  $p < 0.001$ ). The effect persisted regardless of patient location at HT (home, hospital, intensive care) or device type. Discharge by HT occurred in 46% of children in the LVAD group compared with 26% of children in the vasoactive infusion cohort ( $p = 0.001$ ). Stroke was reported at HT in 3% of children in the LVAD cohort and in 1% in the vasoactive infusion cohort ( $p = 0.04$ ).

**CONCLUSIONS:** Among children with dilated cardiomyopathy undergoing HT, children supported with LVADs at HT have higher FS than children supported with vasoactive infusions at HT, regardless of device type or hospitalization status. Children supported with LVADs at HT were more likely to be discharged from the hospital but had a higher prevalence of stroke at HT.

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The use of left ventricular assist devices (LVADs) in children as a bridge to heart transplant (HT) has grown dramatically during the past 10 years. Because LVAD survival for children with dilated cardiomyopathy (DCM) has improved to approximate survival with inotropic support, the choice between medical therapy and device therapy for children awaiting HT may depend more on secondary factors, such as quality of life and functional status (FS), than mortality alone.<sup>1–8</sup> Improved FS is well described in adult LVAD recipients, but limited data are available in children.<sup>7,9</sup> Thus, the primary aims of this study were (1) to assess the FS at HT of children with DCM supported with an LVAD compared with children supported with vasoactive infusions, and (2) to determine whether children supported with LVADs at HT are more likely to be discharged from the hospital. The broader purpose of the study was to determine which treatment strategy provides the optimal quality of life and functional capacity in children with end-stage heart failure awaiting HT.

## Methods

### Study population and data source

All United States (US) children aged between 1 and 21 years with DCM and supported at HT with vasoactive infusions alone or LVAD alone between January 2006 and December 2015 with a FS score available were identified using Organ Procurement and Transplantation Network (OPTN) data. OPTN is an internally audited, mandatory, government-sponsored solid-organ transplant registry that collects information on all solid-organ transplants in the US. Demographic and clinical information is reported by HT centers to the OPTN and is supplemented by data from the Social Security Administration.

The study dates were chosen based on when the UNOS routinely collected FS data as a mandatory variable at the time of listing and transplant. The primary analysis included patients with scores at both time points (time of listing and time of HT). Children younger than 12 months at the time of listing were excluded because OPTN does not collect FS score in infants. Patients on mechanical ventilation, biventricular assist device (BIVAD) support, LVAD and vasoactive infusions, or extracorporeal membrane oxygenation at HT were excluded, as were patients with multiorgan transplants. All patients were monitored until March 31, 2016, when all patients who were still alive were censored.

### Study definitions and outcome measures

The primary study hypothesis was that among children with DCM who underwent HT, children supported with LVADs alone at HT would have superior FS compared with children supported with vasoactive infusions alone at HT. The secondary study hypothesis was that among children with DCM listed for HT, children

supported with LVADs at HT would be more likely to be discharged from the hospital.

A 10-point standardized FS scale, originally developed by Karnofsky and Lansky, was used at the time of HT listing and again at the time of HT ([Supplementary Table](#), available online at [www.jhltonline.org](http://www.jhltonline.org)). The original Karnofsky Scale (designed for adults) and the Lansky Scale (adapted for pediatrics) are widely used assessments validated in adult and pediatric cancer populations<sup>10–13</sup> and were recently used to describe the effect of HT on FS of children with end-stage heart failure.<sup>14</sup> An FS score of 10 denotes a child who is “fully active, normal,” whereas an FS score of 1 represents a child who has “no play and does not get out of bed.”

Race/ethnicity data were analyzed as reported by the transplanting center and included white, black, Hispanic, and other. Glomerular filtration rate was estimated using the modified Schwartz formula.<sup>15</sup> Hemodynamic support at time of listing was analyzed using previously described categories: oral therapy, inotropes, VAD, mechanical ventilation, and extracorporeal membrane oxygenation known to be associated with outcome.<sup>16</sup> Stroke at transplant was defined as a history of stroke at any point before HT and was analyzed as reported by centers. None of the children had missing data for the variables of age, blood type, gender, race/ethnicity, listing status, cardiopulmonary support, location at time of HT, and listing year during the study period.

### Statistical analysis

Summary statistics are presented as median (25th, 75th percentile) or number (%). Patient characteristics were compared across study groups using the Fisher exact test for categorical variables and the Mann-Whitney test for continuous variables. The Mann-Whitney test was used to compare the FS score at time of HT and to compare the change in the FS score while on the waiting list between the 2 groups. The Kaplan-Meier method was used to estimate survival after HT. Analyses were performed using R 3.3.1 software (The R Foundation for Statistical Computing).

## Results

Between January 2006 and December 2015, 701 children aged 1 to 21 years with DCM underwent HT and met the study inclusion criteria. At HT, 430 (61%) were supported on vasoactive infusions alone and 271 (39%) were supported with an LVAD alone. The baseline characteristics of the study cohort are summarized in [Table 1](#). Children supported with an LVAD were an average of 2 years older than those supported with vasoactive infusions (15 vs 13 years,  $p = 0.02$ ), were more likely to be on a higher level of hemodynamic support at listing ( $p < 0.001$ ), were more likely to be on dialysis at listing ( $p < 0.001$ ), and waited longer to receive a donor heart ( $p < 0.001$ ). The difference in renal function between the 2 groups as assessed by the estimated glomerular filtration rate was not significant; however, comparisons using other indices of renal function,

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