

## Original Article

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**Abstract**

**Background:** This study describes the illness burden in the first year of life for children with single-ventricle heart disease, using the metric of days alive and out of hospital to characterize morbidity and mortality. **Methods:** This is a retrospective single-centre study of single-ventricle patients born between 2005 and 2021 who had their initial operation performed at our institution. Patient demographics, anatomical details, and hospitalizations were extracted from our institutional single-ventricle database. Days alive and out of hospital were calculated by subtracting the number of days hospitalized from number of days alive during the first year of life. A multivariable linear regression with stepwise variable selection was used to determine independent risk factors associated with fewer days alive and out of hospital. **Results:** In total, 437 patients were included. Overall median number of days alive and out of hospital in the first year of life for single-ventricle patients was 278 days (interquartile range 157–319 days). In a multivariable analysis, low birth weight (<2.5kg) ( $b = -37.55$ ,  $p = 0.01$ ), presence of a dominant right ventricle ( $b = -31.05$ ,  $p = 0.01$ ), moderate-severe dominant atrioventricular valve regurgitation at birth ( $b = -37.65$ ,  $p < 0.05$ ), index hybrid Norwood operation ( $b = -138.73$ ,  $p < 0.01$ ), or index heart transplant ( $b = -158.41$ ,  $p < 0.01$ ) were all independently associated with fewer days alive and out of hospital. **Conclusions:** Children with single-ventricle heart defects have significant illness burden in the first year of life. Identifying risk factors associated with fewer days alive and out of hospital may aid in counselling families regarding expectations and patient prognosis.

CHD with single-ventricle physiology is a heterogeneous set of structural abnormalities characterised by the presence of only one ventricle capable of supporting systemic circulation. Estimates of the prevalence of single-ventricle heart disease range from 0.08 to 0.4 per 1,000 live births.<sup>1,2</sup> When counselling families regarding the prognosis of patients with CHD, data suggest there are discrepancies between physician and parent expectations and perceptions of prognosis.<sup>3,4</sup> This discordance highlights the need for an outcome measure that both captures illness burden and can be understood by the patient's families. Days alive and out of hospital is a patient-centred outcome that is being increasingly used as a metric to quantify the morbidity and mortality of surgical procedures and interventions.<sup>5,6,7</sup> This metric has been demonstrated as an effective way to capture illness burden, but there remains a paucity of literature regarding the metric of days alive and out of hospital in patients with CHD, particularly single-ventricle patients.<sup>5,6</sup>

While single-ventricle heart disease represents a diverse array of anatomic malformations, children are typically progressed through similar staged palliative surgeries. However, despite these similar management pathways, outcomes can vary dramatically between different subgroups.<sup>8,9</sup> The delivery of a diagnosis of single-ventricle CHD often brings up concerns among family members regarding the general course of care in the patient's early life and likelihood of survival through staged palliations.<sup>10</sup> The aim of this study is to provide a more comprehensive overview of morbidity, mortality, and overall illness burden in the first year of life for different morphological subgroups of single-ventricle patients using the primary metric of days alive and out of hospital in the first year of life.

**Materials and methods**

This study received approval from the Duke Institutional Review Board (Pro00101549, January 2019). The need for individual consent is waived due to the retrospective nature of the study.

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### Cohort selection and data acquisition

This is a retrospective study of all single-ventricle patients born between the years 2005 to 2021 at our institution. Data on patient demographics, anatomy, and operative management was extracted from our institutions' prospectively maintained single-ventricle database.<sup>8</sup> All other data were collected via a retrospective chart review. Single-ventricle heart disease was defined as patients with a hypoplastic or dysfunctional ventricle whose candidacy for biventricular repair was either unattainable or uncertain after evaluation by the congenital heart team. Patients who did not have their primary operation at our institution were excluded from analysis. Patients who were alive but did not have available follow-up records beyond ten months of age were excluded from our analysis to improve accuracy of overall mortality and number of days alive and out of hospital in the first year of life.

### Days alive and out of hospital

We calculated days alive and out of hospital in the first year of life by subtracting the number of days the patient was admitted to the hospital from the number of days the patient was alive during the first year of life. Any emergency department visits resulting in same-day discharge or outpatient procedures were not included in the final number of days hospitalised. External care records were reviewed when available to include hospitalisations at other institutions.

### Statistical analysis & multivariable modelling

Descriptive statistics and hypothesis testing were used to compare baseline characteristics, number of days alive and out of hospital and secondary endpoints between different single-ventricle subgroups. Continuous variables were reported as mean and standard deviation or as median and interquartile range (25–75%) depending on normality as assessed using the Shapiro-Wilks test. Categorical data were presented as counts (n) with corresponding percentages (%).

A multivariable linear regression with a stepwise variable selection procedure was used to determine risk factors independently associated with fewer days alive and out of hospital. In multivariable analysis, surgical era was divided into early (February 8<sup>th</sup>, 2005–June 30<sup>th</sup>, 2013) and late (July 1<sup>st</sup>, 2013–December 22<sup>nd</sup>, 2021) eras to account for differences in surgical techniques. A  $p$ -value  $< 0.05$  was considered statistically significant. All analyses were performed using R version 4.1.2 (R Foundation for Statistical Computing, Vienna, Austria).

### Sensitivity analysis

To ensure that risk factors included in our multivariable analysis were associated with fewer days alive and out of hospital and not significantly influenced by in-hospital mortality, we performed a sensitivity analysis. In this sensitivity analysis, we excluded all patients who died during their index hospitalisation (i.e. 0 days alive and out of hospital) and then reanalysed using our multivariable regression model.

## Results

### Baseline characteristics

A total of 437 single-ventricle patients met inclusion criteria for analysis. Our cohort consisted of a heterogeneous mixture of

fundamental diagnoses and index operations, the most common fundamental diagnosis being hypoplastic left heart syndrome ( $n = 154$ , 35%), and most common overall index operation being the Norwood procedure ( $n = 196$ , 45%). Detailed baseline characteristics are summarised in Supplemental Table 1.

### Days alive and out of hospital

#### Fundamental diagnosis

Overall median number of days alive and out of hospital in the first year of life was 278 days (157–319 days). Patients were divided into eight different subgroups based on anatomical subtype. Hypoplastic left heart syndrome ( $n = 154$ , 35%) patients had the fewest number of days alive and out of hospital with a median of 248 days (65–308 days), while patients with tricuspid atresia ( $n = 38$ , 9%) had the greatest number of days alive and out of hospital with a median of 308 days (272–335 days). Median number of days alive and out of hospital for all single-ventricle subgroups are demonstrated in Figure 1 and Supplemental Table 2.

#### Index procedure

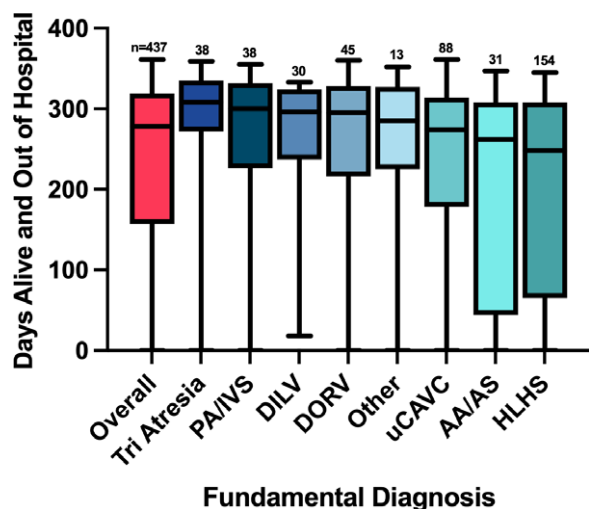
Patients were divided into eleven different index procedures based on initial type of palliation. Patients who did not undergo any initial surgical palliation ( $n = 18$ , 4%) had the greatest number of days alive and out of hospital in the first year of life with a median number of 336 days (305–353 days), while patients undergoing a primary surgery of hybrid Norwood ( $n = 12$ , 3%) had the fewest number of days alive and out of hospital with a median of 0 days (0–294 days). Median number of days alive and out of hospital by index procedure is detailed in Figure 2 and Supplemental Table 3.

### Predictive factors for fewer days alive and out of hospital

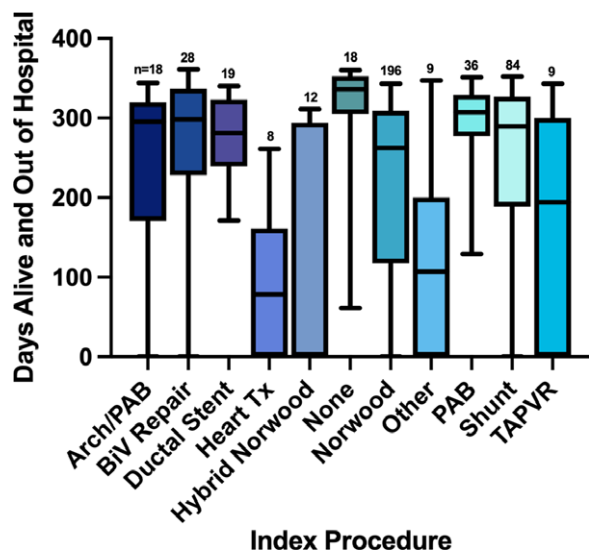
After stepwise variable selection was completed, index procedures of heart transplant ( $b = -158.41$ ,  $p < 0.01$ ) and hybrid Norwood ( $b = -138.73$ ,  $p < 0.01$ ) were shown to be significant predictors of fewer days alive and out of hospital in the first year of life, along with moderate-to-severe dominant atrioventricular valve regurgitation at birth ( $b = -37.65$ ,  $p < 0.05$ ), right ventricular dominance ( $b = -31.05$ ,  $p = 0.01$ ), and low birth weight ( $< 2.5$  kg) ( $b = -37.55$ ,  $p = 0.01$ ). Surgical era did not significantly contribute to fewer days alive and out of hospital. Results of the multivariable analysis are presented in Table 1.

### Sensitivity analysis

Excluding patients with zero days alive and out of hospital, we were left with a final cohort of 381 patients with which to carry out our sensitivity analysis. Stepwise variable selection was again performed and the following risk factors were associated with fewer days alive and out of hospital in the first year of life in those without in-hospital mortality: non-cardiac anatomic abnormality ( $b = -6.56$ ,  $p < 0.01$ ), gestational age ( $b = 6.78$ ,  $p < 0.01$ ), moderate-severe dominant atrioventricular valve regurgitation at birth ( $b = -48.63$ ,  $p < 0.01$ ), and index procedure of heart transplant ( $b = -128.47$ ,  $p < 0.01$ ). Results of the sensitivity analysis are presented in Table 2. Median days alive and out of hospital and baseline characteristics of the sensitivity analysis cohort are provided in Supplemental Tables 4 and 5, respectively.



**Figure 1.** Box and whisker plot of days alive and out of hospital for single-ventricle subgroups in the first year of life demonstrating median, minimum, and maximum values, along with first and third quartiles.



**Figure 2.** Box and whisker plot of days alive and out of hospital for single-ventricle subgroups in the first year of life by index procedure demonstrating median, minimum, and maximum values, along with first and third quartiles.

**Discussion**

This study identified risk factors associated with fewer days alive and out of hospital in the first year of life for single-ventricle patients and quantified the number of days alive and out of hospital. Through multivariable analysis, notable risk factors for fewer days alive and out of hospital were index procedures of heart transplant and hybrid Norwood, moderate-to-severe dominant atrioventricular valve regurgitation at birth, right ventricular dominance, and low birth weight (<2.5 kg). While other studies have focused on characterising the number of days alive and out of hospital within 30 days of operation or in the first year of life for hypoplastic left heart syndrome patients, there are few studies that have quantified the number of days alive and out of hospital for multiple single-ventricle subgroups.<sup>11-13</sup> Overall median number of days alive and out of hospital in the first year of life for patients with a single-ventricle diagnosis was 278 days.

Unsurprisingly, hypoplastic left heart syndrome patients had the fewest median number of days alive and out of hospital at 248 days and patients with tricuspid atresia had the greatest number at 308 days. Patients with no index palliation had the greatest median number of days alive and out of hospital at 336 days and those undergoing initial hybrid Norwood had the fewest number at 0 days.

Single-ventricle patients demonstrate heterogeneous anatomic lesions, and median number of days alive and out of hospital varied between anatomic subtypes. This difference in days alive and out of hospital could partly be attributed to the dominant ventricle present among the lesion types and forms of initial intervention. For example, patients with tricuspid atresia, pulmonary atresia with intact ventricular septum, and double inlet left ventricle had the greatest median number of days alive and out of hospital in the first year of life. These subgroups all have a dominant left ventricle and tend to undergo less invasive initial palliations, such as shunts, pulmonary artery bands, and ductal stents, which likely contribute to their greater number of days alive and out of hospital.<sup>8,14,15</sup> Kalustian et al demonstrate that in single-ventricle patients undergoing pulmonary artery banding versus modified Norwood procedure, those undergoing pulmonary artery banding had significantly shorter post-operative lengths of stay.<sup>16</sup> Similarly, patients undergoing ductal stents and shunts had relatively short initial hospital lengths of stay. Those undergoing ductal stenting had shorter index hospitalisations, although were at risk for acute stent dysfunctions.<sup>17</sup> Conversely, patients with hypoplastic left heart syndrome, aortic atresia/aortic stenosis, and right ventricle dominant unbalanced atrioventricular canal had the fewest number of days alive and out of hospital. These patients were all right ventricle dominant and underwent index palliations that included the Norwood operation, heart transplant, and total anomalous pulmonary venous return repair. These findings are similar to what has been demonstrated in other studies that patients undergoing heart transplant at < 3mo of age or with single-ventricle physiology have higher rates of early mortality and thus, less time spent out of the hospital.<sup>18</sup> Additionally, patients undergoing total anomalous pulmonary venous return repair are shown to have poor long-term survival, further demonstrating this to be a high-risk population that may require more healthcare resources.<sup>19</sup>

Multivariable analysis identified risk factors associated with fewer days alive and out of hospital in the first year of life including index operation of hybrid Norwood or heart transplant. Newborn single-ventricle patients requiring heart transplant typically have severe single-ventricle disease not amenable to standard single-ventricle palliation and generally require in-patient hospitalisation while awaiting a donor organ. Everitt et al identified that patients with hypoplastic left heart syndrome who receive a heart transplant, particularly those with prior surgery, have lower rates of 1, 5, and 10-year survival relative to patients with heart transplant due to cardiomyopathy, consistent with our analysis.<sup>20</sup> Our finding that hybrid Norwood is a risk factor for fewer days alive and out of hospital is likely centre specific and consistent with our institutional approach of only using the hybrid Norwood for high-risk patients who are not considered candidates for cardiopulmonary bypass. Other centres have demonstrated that the hybrid Norwood approach can have comparable outcomes to the traditional Norwood palliation.<sup>8,21</sup> Notably, surgical era did not impact days alive and out of hospital, indicating that while advances in surgical techniques and post-operative care between 2005 and 2021 may have some influence on the outcomes of our single-ventricle patients, underlying cardiac anatomy and baseline

**Table 1.** Results of multivariable regression identifying risk factors for fewer days alive and out of hospital in the first year of life

Covariate	Coefficient		
	Coefficient Estimate	Standard Error	p-value
Chromosomal Abnormality or Genetic Syndrome	−28.06	14.32	0.05
Late Era	17.61	11.78	0.14
Moderate/Severe Dominant Atrioventricular Valve Regurgitation	−37.65	19.13	<0.05
Right Ventricle Dominant	−31.05	12.55	0.01
Non-cardiac Anatomic Abnormality	−29.23	18.48	0.11
Low Birth Weight	−37.55	15.04	0.01
Index Proc = BiV Repair	11.09	32.91	0.74
Index Proc = Ductal Stent	29.84	35.87	0.41
Index Proc = Heart Tx	−158.41	45.86	<0.01
Index Proc = Hybrid Norwood	−138.73	40.11	<0.01
Index Proc = Norwood	−37.98	26.89	0.16
Index Proc = PAB	39.70	31.12	0.20
Index Proc = Shunt	−21.12	28.65	0.46
Index Proc = TAPVR	−63.55	44.19	0.15
Index Proc = None	41.61	36.31	0.25

**Table 2.** Results of sensitivity analysis identifying risk factors for fewer days alive and out of hospital in those surviving index hospitalisation

Covariate	Coefficient		
	Coefficient Estimate	Standard Error	p-value
Gestational Age	6.78	2.26	<0.01
Moderate/Severe Dominant Atrioventricular Valve Regurgitation	−48.63	15.72	<0.01
Right Ventricle Dominant	−15.51	9.88	0.12
Non-cardiac Anatomic Abnormality	−36.56	13.99	<0.01
Index Proc = BiV Repair	4.39	25.84	0.87
Index Proc = Ductal Stent	10.79	28.27	0.70
Index Proc = Heart Tx	−128.47	41.51	<0.01
Index Proc = Hybrid Norwood	−0.99	45.59	0.98
Index Proc = Norwood	−37.91	21.44	0.08
Index Proc = PAB	15.55	24.41	0.52
Index Proc = Shunt	−37.23	22.67	0.10
Index Proc = TAPVR	−12.76	39.26	0.75
Index Proc = None	24.82	28.05	0.38

risk factors continued to be the most important determinants of mortality and hospitalisation.

Other risk factors that reached significance in our model such as moderate-to-severe dominant atrioventricular valve regurgitation at birth, right ventricular dominance, and low birth weight all behave similarly to other studies of risk factors for survival or prolonged hospitalisations within the single-ventricle subgroups.<sup>22–25</sup> While these well-known risk factors for survival or prolonged hospitalisation for single-ventricle patients are difficult to optimise prior to surgical intervention, they are still important details to consider when managing expectations for families and providers regarding healthcare burden in the first year of life.

By excluding patients who did not survive their index hospitalisation, we were able to identify factors that affect long-term days alive and out of hospital.<sup>26</sup> This identified that gestational age and presence of non-cardiac anatomic defects were associated with increased rehospitalization and thus fewer days alive and out of hospital, while hybrid Norwood and right ventricular dominance no longer impacted days alive and out of hospital if a patient survived index hospitalisation. This change in variable significance of non-cardiac anatomic abnormalities in adjusted analyses has also been demonstrated in a study by Alsoofi et al.<sup>27</sup> It is possible that children with extra-cardiac defects, after surviving their index hospitalisation, require a higher level of

general care that contributes to more frequent hospitalisations in this population. Prematurity has also been demonstrated in larger studies to be a factor that significantly contributes to fewer days alive and out of hospital in the first year of life.<sup>25</sup> Overall, this analysis highlights important factors to consider when thinking about the prognosis of these patients and their days alive and out of hospital in the first year of life.

### Limitations

This was a retrospective, single-centre cohort study with a limited sample size, particularly for certain single-ventricle subgroups, so our results may have limited external applicability. However, most of our outcomes are consistent with what is presented in the literature and thus could be regarded as representative. Additionally, the ability to utilise institutional data and a retrospective chart review allows for the opportunity to collect granular data that may not be present in large national databases. As with most retrospective projects, there are limitations with the medical record, and it is not guaranteed that every hospitalisation was recorded and included in our study. Despite this, there have been increasing efforts to provide coordinated and collaborative care for our single-ventricle patients by promoting communication with adjacent centres, thus the likelihood that hospitalisations go unrecorded in the medical record has decreased. Days alive and out of hospital in the first year of life likely also varies significantly between institutions based on discharge practices, distance from hospital, or institutional policy regarding discharge prior to Stage 2 palliation for higher-risk single-ventricle patients. Lastly, with patients being included over a long study period, there will naturally be bias associated with different eras of care. Advances in technology, operative techniques, and interstage management of these patients could influence the number of days alive and out of hospital in the first year of life for our patients. To mitigate this potential era bias, we included era in our final multivariable model and found that it did not significantly contribute to the number of days alive and out of hospital in the first year of life for our single-ventricle patients.

### Conclusion

Key factors influencing number of days alive and out of hospital in the first year of life for patients with single-ventricle heart disease were primarily index procedures of heart transplantation and hybrid Norwood along with elements of underlying cardiac anatomy and patient characteristics. These data provide important insight into illness burden that single-ventricle patients and their families face during the first year of life. Similarly, characterisation of risk factors for fewer days alive and out of hospital in the first year of life can serve to guide clinicians during discussions regarding family expectations and patient prognosis.

**Supplementary material.** The supplementary material for this article can be found at <https://doi.org/10.1017/S1047951124000118>.

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**Competing interests.** None.

**Ethical standards.** The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national guidelines on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008, and has been approved by the Duke Institutional Review Board (Pro00101549, January 2019).

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