Extracorporeal Membrane Oxygenation for Bridge to Heart Transplantation Among Children in the United States
Analysis of Data From the Organ Procurement and Transplant Network and Extracorporeal Life Support Organization Registry

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Background—Extracorporeal membrane oxygenation (ECMO) has served for >2 decades as the standard of care for US children requiring mechanical support as a bridge to heart transplantation. Objective data on the safety and efficacy of ECMO for this indication are limited. We describe the outcomes of ECMO as a bridge to heart transplantation to serve as performance benchmarks for emerging miniaturized assist devices intended to replace ECMO.

Methods and Results—Data from the Extracorporeal Life Support Organization Registry and the Organ Procurement and Transplant Network database were merged to identify children supported with ECMO and listed for heart transplantation from 1994 to 2009. Independent predictors of wait-list and posttransplantation in-hospital mortality were identified. Objective performance goals for ECMO were developed. Of 773 children, the median age was 6 months (interquartile range, 1 to 44 months); 28% had cardiomyopathy; and in 38%, a bridge to transplantation was intended at ECMO initiation. Overall, 45% of subjects reached transplantation, although one third of those transplanted died before discharge; overall survival to hospital discharge was 47%. Wait-list mortality was independently associated with congenital heart disease, cardiopulmonary resuscitation before ECMO, and renal dysfunction. Posttransplantation mortality was associated with congenital heart disease, renal dysfunction, ECMO duration of >14 days, and initial ECMO indication as a bridge to recovery. In the objective performance goal cohort (n=485), patients with cardiomyopathy had the highest survival to hospital discharge (63%), followed by patients with myocarditis (59%), 2-ventricle congenital heart disease (44%) and 1-ventricle congenital heart disease (33%).

Conclusion—Although ECMO is effective for short-term circulatory support, it is not reliable for the long-term circulatory support necessary for children awaiting heart transplantation. Fewer than half of patients bridged with ECMO survive to hospital discharge. More effective modalities for chronic circulatory support in children are urgently needed. (Circulation. 2011;123:2975-2984.)

Key Words: heart defects, congenital ■ extracorporeal membrane oxygenation ■ outcome assessment ■ pediatrics ■ transplantation ■ heart failure ■ heart-assist device
ECMO as a bridge to transplantation.21-23 Yet, because ECMO has never been formally reviewed by the FDA for this indication, comprehensive benchmark data on the safety and efficacy of ECMO as a bridge to heart transplantation are lacking. Published reports have been limited to single-institution experiences1-9 with success rates that vary considerably by center and/or case mix, with limited power to adjust simultaneously for multiple confounders or to perform important subgroup analyses (eg, single-ventricle patients). Previous reports have also generally lacked a dedicated safety analysis for ECMO2-9 or independent confirmation that analyzed subjects were indeed officially listed for transplantation.

To address these limitations, we combined data from 2 multicenter databases to identify a large cohort of children supported with ECMO as a bridge to transplantation for whom relatively complete safety and efficacy information was available. The Extracorporeal Life Support Organization (ELSO) Registry24 is an international registry that collects detailed information on patients supported with ECMO and includes adverse events; the Organ Procurement and Transplant Network (OPTN) database25 collects detailed information on all US heart transplantation candidates and includes wait-list and posttransplantation outcomes. Together, their collective strengths offer a unique opportunity to better understand the safety and efficacy of ECMO as a bridge to transplantation. We also tested the hypothesis that ECMO duration is independently associated with in-hospital mortality, information that may be useful to clinicians in determining the optimal timing of transition from ECMO to VAD therapy and to policy makers as they re-evaluate the current organ allocation system for pediatric donor hearts.26

Therefore, the specific objectives of this study were to describe the safety and efficacy profile of ECMO as a bridge to heart transplantation in children, to develop objective performance goals for ECMO as a bridge to transplantation, and to determine whether ECMO duration is associated with in-hospital mortality. By developing benchmark data on the safety and efficacy profile of ECMO as a bridge to transplantation in children, we hope to provide a stronger context within which to understand the safety and performance of the next generation of cardiac assist devices.

**Methods**

**Study Population and Data Source**

The OPTN database and ELSO Registry were used to identify all children <18 years of age who were supported with venoarterial ECMO and listed for orthotopic heart transplantation in the United States between January 1, 1994, and February 20, 2009. The OPTN database collects demographic and clinical information on all wait-list candidates and all transplant recipients in the United States as submitted by the transplantation centers. The ELSO Registry is a multicenter registry that collects detailed clinical information on patients supported with ECMO, including adverse events, using standardized definitions. Individual patient records were matched between databases using an algorithm involving patient date of birth, date of ECMO, listing date, and center code. Patients listed for heart retransplantation or multiorgan transplantations were excluded. All patients were followed up from the time of listing for heart transplantation until discharge from the hospital, death, or the day of last observation on February 25, 2009. The study protocol was approved by the Committee on Clinical Investigation at Children’s Hospital Boston and the Health Research Services Administration of the US Department of Health and Human Services.

**Study Definitions and Outcome Measures**

Bridge to transplantation was defined as the use of ECMO as a strategy for reaching heart transplantation regardless of the ultimate outcome (transplantation, death, or recovery) or original intent for ECMO as recorded by centers at the time of initial ECMO cannulation. The latter is in recognition of the fact that some children are placed on ECMO initially with the intent to obtain myocardial recovery but are subsequently changed to bridge to transplantation if/when myocardial recovery fails to occur. Duration of ECMO was defined as duration in days from the first ECMO cannulation to the first ECMO decannulation. Total ECMO duration (cumulative number of days) for subjects receiving ECMO support more than once was also examined for association with outcome. The primary end point was removal from the wait list because of death or clinical deterioration. The secondary end point was death after transplantation but before hospital discharge in those who received a heart transplantation. Wait-list and posttransplantation outcomes were analyzed on an intention-to-treat basis. Patients were eligible to receive any form of medical or mechanical support available at the time of ECMO support, including VAD, balloon pump, or other circulatory support device. For analysis of wait-list mortality, all clinical and demographic variables were defined at the time of ECMO cannulation or transplantation listing when appropriate. For analysis of posttransplantation mortality, all clinical and demographic variables were defined at the time of transplantation. Cardiac diagnosis was analyzed as reported by ECMO centers and categorized into 1 of 4 categories: cardiomyopathy, myocarditis, congenital heart disease (CHD) with a 2-ventricle circulation, or CHD with a 1-ventricle circulation (inclusive of all stages). Race/ethnicity categories (black, white, Hispanic, and other) were analyzed as reported by the transplantation center. Creatinine clearance was estimated from the Schwartz formula27 and categorized as normal, severely decreased if the creatinine clearance was <50% of the lower limit of normal for age, or moderately decreased for all values in between. Adverse events on ECMO were analyzed as reported to the ELSO Registry using standardized definitions.24

Because some patients supported with ECMO over the past 15 years would not be considered candidates for early pediatric VAD trials owing to such factors as severe end-organ dysfunction (eg, dialysis), extremes of patient size, or certain anatomic considerations, we created a secondary cohort of patients that removed these patients to develop objective performance goals for ECMO that can serve as performance benchmarks for emerging cardiac assist devices entering into clinical trials. Patients with the following characteristics were excluded: weight ≤2.9 kg, weight >50 kg, severe renal dysfunction, total bilirubin >2.0 mg/dL, brain death within 48 hours of ECMO cannulation, and diagnosis of restrictive cardiomyopathy or hypertrophic cardiomyopathy.

**Statistical Analysis**

Summary statistics are presented as median (interquartile range) or number (percent). Patient characteristics were compared across cardiac diagnostic subgroups by use of the χ² test for categorical variables and the Kruskal-Wallis test for continuous variables. Univariate associations of patient characteristics and both wait-list mortality and posttransplantation mortality were evaluated by use of logistic regression. Multivariable logistic regression models were developed for the primary and secondary end points through the use of forward selection. Variables significant at the 0.20 level in unadjusted analyses were considered for inclusion; only variables significant at the 0.05 level based on the likelihood ratio test were retained in the final model. Adverse events on ECMO were assessed.
by frequency and type as reported to the ELSO Registry by ECMO centers. Standard descriptive statistics were used to determine the proportion of patients surviving to transplantation and hospital discharge in the objective performance goal cohort and the frequency and rate of serious adverse events in this cohort. Finally, we performed a competing-risk analysis to illustrate multiple possible outcomes (death, transplantation, recovery, and alive and waiting) at any point in time in the objective performance goal cohort with different cardiac diagnoses. Unless otherwise stated, recovery is defined as patient removal from the heart transplantation wait list because of myocardial recovery. The data were analyzed with SAS version 9.1 (SAS Institute Inc, Cary, NC) and STATA version 10.0 (StataCorp LP, College Station, TX).

The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

Results

Study Cohort

Of 8018 children listed for a heart transplantation in the United States during the study period, 773 subjects met the inclusion criteria (9.6% of listed patients). Children listed for heart transplantation were excluded for the following reasons: 7073 (88.3%) for no ECMO support, 151 (1.9%) for retransplantation, 1 (<0.1%) for multiorgan transplant, and 20 (0.2%) for no cardiac diagnosis reported. Table 1 summarizes baseline characteristics in the study cohort. Overall, the median age was 6 months; median weight was 6.6 kg; 45% were female; and 34% were nonwhite. The primary cardiac diagnosis leading to heart transplantation listing was CHD in 64% (34% with a 2-ventricle circulation and 30% with a 1-ventricle circulation); cardiomyopathy was the primary cardiac diagnosis in 28% of the subjects and myocarditis in 8% of the subjects.

Survival to Transplantation and Hospital Discharge

Figure 1 summarizes overall patient survival in children supported with ECMO as a bridge to transplantation. Among 773 subjects, 346 children (45%) survived to transplantation; 79 (10%) were removed from the wait list because of recovery, 217 (28%) died while on the wait list, 84 (11%) were removed owing to clinical deterioration; and 47 (6%) were alive and on the wait list on February 25, 2009, the last day of the study. The median duration of ECMO support for patients who died on the wait list while on ECMO was 10.4 days (interquartile range, 4 to 21 days). Overall survival to
hospital discharge was 47% for patients bridged with ECMO but varied according to cardiac diagnosis (61% for patients with myocarditis, 55% for cardiomyopathy, 39% for 2-ventricle CHD, and 27% for 1-ventricle CHD).

Risk Factors for Wait-List and Posttransplantation Mortality
Table 2 summarizes the univariate and multivariable predictors of wait-list mortality using ECMO as the support strategy and of posttransplantation in-hospital mortality for those who received a heart transplantation. Independent predictors of mortality on the wait list included 2-ventricle CHD, 1-ventricle CHD, severe renal dysfunction, and cardiopulmonary resuscitation before ECMO. Among transplantation recipients, factors independently associated with wait-list and posttransplantation mortality include 2-ventricle CHD, 1-ventricle CHD, and renal dysfunction. Wait-list mortality was also associated with cardiopulmonary resuscitation before ECMO, whereas posttransplantation mortality was associated with ECMO duration of >14 days and initial indication for ECMO not for bridge to transplantation. Of note, era of ECMO support was not associated with either wait-list mortality or posttransplantation mortality in adjusted analyses.

Adverse Events on Extracorporeal Membrane Oxygenation
Table 3 summarizes the frequency of adverse events in the study cohort. Overall, bleeding (46%), arrhythmia (26%), device thrombus (24%), and device malfunction (23%) were the most common adverse events. Infection and neurological events were also common and reported in 17% and 16% of children, respectively.

Extracorporeal Membrane Oxygenation and Objective Performance Goals
In the objective performance goal cohort (n=485, 63%), overall survival to heart transplantation for children bridged with ECMO was 43% (55% in children with cardiomyopathy, 37% in children with CHD). Figure 2 depicts wait-list competing outcomes for the objective performance goal.
cohort according to cardiac diagnosis. Table 3 summarizes the frequency of serious adverse events for the overall cohort and the objective performance goal cohort. On the basis of the wait-list and posttransplantation outcomes in this cohort, proposed objective performance goals for ECMO as a bridge to transplantation are presented in Table 4. Overall in-hospital mortality varied considerably by diagnosis (survival to hospital discharge was 63% for children with cardiomyopathy, 44% for children with 2-ventricle CHD, and 33% for children with 1-ventricle CHD).

**Discussion**

In this study, we found that since the mid-1990s in the United States, more than half of all children supported with ECMO as a bridge to heart transplantation failed to survive to hospital discharge. The majority of deaths occurred while the children were on the wait list, but children who were successfully bridged to transplantation also had high posttransplantation mortality, accounting for up to one third of all in-hospital deaths for this cohort. The risk of death was not uniform across all patient groups and varied by as much as 2-fold (33% to 69%) on the basis of cardiac diagnosis alone. Other patient factors associated with in-hospital mortality included severe renal dysfunction, duration of ECMO support of >14 days, and initial ECMO indication of bridge to recovery. Factors such as ECMO era and patient size were not associated with survival.

These findings are consistent with earlier reports that found ECMO to be successful in bridging anywhere from 35% to
65% of children to transplantation and 28% to 58% of children to hospital discharge. In the largest series of 46 children published by a Toronto group, BarZiv and colleagues found that 65% survived to transplantation or recovery and 56% survived to hospital discharge. However, this and other single-institution studies of ECMO have been limited by small sample size and uncertain generalizability resulting from regional differences in both ECMO practices and organ availability. In contrast, the present report, in summarizing the outcomes of >700 US children in whom ECMO was used in an effort to bridge children safely to transplantation, represents by far the largest study on this topic to date. To the best of our knowledge, this is the first study to systematically describe the safety and efficacy of ECMO as a bridge to heart transplantation using national data with adverse event definitions standardized across centers, to describe the wide variation in survival rates stemming from the heterogeneity of the ECMO population, to propose objective performance measures for ECMO as a bridge to transplantation that may serve as benchmarks for emerging pediatric assist devices intended for bridge to transplantation, and to single out ECMO duration itself as an independent predictor of mortality.

We were rather surprised to find that ECMO era was not associated with survival after adjustment for patient factors. This finding is important because defining precisely how far back in time the contemporary ECMO era extends is essential to avoid a performance bias introduced by analyzing subjects across eras. The lack of era effect in ECMO outcomes stands as a notable exception to many trends in transplantation medicine but is consistent with other studies that have found cardiac ECMO outcomes to be strikingly constant over the past 20 years.

The findings of this study have several important implications. First, our findings confirm what many have long suspected, that although ECMO is highly effective for short-term circulatory support, it is not capable of providing the kind of reliable long-term circulatory support necessary for bridging children safely to heart transplantation. Given current US waiting times and organ allocation practices, the median ECMO duration of 10.3 days represents just 15% of the median waiting time for an infant to receive a donor heart in the United States and 31% of the median waiting time for an older child (Figure 3). With just 1 of every 2 patients bridged with ECMO surviving to hospital discharge, our findings underscore why children awaiting heart transplantation have faced the single highest wait-list mortality in solid-organ transplant medicine and emphasize the urgency behind the National Heart, Lung, and Blood Institute’s initiative to develop more reliable miniaturized assist devices for the smallest patients. Moreover, these data also provide further evidence to support the American Heart Association scientific statement on indications for pediatric heart transplantation for patients with Class D heart failure.

The finding that the mortality associated with ECMO is not confined to the waiting period may also have important implications for the design of clinical trials for pediatric assist devices intended to replace ECMO. The reason is that survival to heart transplantation—the traditional clinical end point for bridge to heart transplantation studies—may significantly underestimate the mortality attributable to ECMO by overlooking the excess mortality observed immediately after transplantation. For comparative analyses involving ECMO, pediatric study planners may wish to consider using survival to hospital discharge rather than survival to transplantation as a primary study end point.

Second, our findings indicate that, although overall patient survival for ECMO as a bridge to transplantation is poor, the risk of death cannot be viewed as monolithically high for all children bridged with ECMO. Rather, the multivariable analysis suggests that the cohort is remarkably heterogeneous with wide variation in the risk of mortality based on patient-specific factors. Moreover, ECMO patients can be risk stratified separately for their risk of death while awaiting transplantation and secondly early after transplantation, which could help guide thorny candidate selection decisions surrounding transplant listing, VAD support, and conceivably organ allocation policy. For example, our data suggest that a child with cardiomyopathy with preserved end-organ function supported for <2 weeks on ECMO is a relatively favorable candidate for transplantation (>90% chance of surviving to hospital discharge), whereas a single-ventricle patient with significant renal dysfunction supported for >2 weeks is highly unlikely to survive to discharge despite an ideal heart offer for transplantation.
Lastly, our findings suggest that despite the marked heterogeneity of the patient population, sufficient numbers of more conventional-risk patients exist to formulate objective performance goals for ECMO that may be useful as clinical benchmarks for understanding the performance of emerging cardiac assist devices intended to replace ECMO. One of the greatest challenges facing the FDA approval process for pediatric microcurrent stimulation devices—and for high-risk medical devices throughout pediatrics—is the FDA requirement to demonstrate that an emerging device is associated with “probable benefit and a reasonable assurance of safety,” the legal threshold for FDA approval under the humanitarian device regulation,30,31 despite small sample size and significant patient heterogeneity. Assembling objective benchmark data for ECMO provides a stronger clinical context within which to

Figure 2. Wait-list outcomes according to cardiac diagnosis in the objective performance goal cohort (n=485). A, All patients; B, cardiomyopathy; C, myocarditis; D, congenital heart disease (CHD); E, CHD, 2-ventricle circulation; F, CHD, 1-ventricle circulation. Blue denotes the proportion of children who received transplants; purple, the proportion of children who recovered; red, the proportion of patients who died; and green, the proportion of patients still waiting.
understand and potentially demonstrate the probable benefit and reasonable safety of promising pediatric support devices, which may ultimately help avoid unnecessary delays in securing access to potentially lifesaving devices available for children.21,22

The study has several limitations related to its retrospective study design. First, retrospective studies are susceptible to selection bias if the selected sample poorly represents the larger population. However, because our case selection process involved a query of 2 separate and independent databases, we believe we were able to capture the vast majority of children supported with ECMO as a bridge to transplantation in the United States, minimizing this risk. Likewise, adverse events and cardiac diagnosis were analyzed as recorded by ECMO and transplant centers, which carries the risk of disease misclassification (eg, diagnosis of myocarditis). Second, data were missing for renal function on a number of patients in our study; however, we were reassured to find that overall outcomes, multivariable analysis, and objective performance goal estimates did not change appreciably when the analysis was restricted to patients with nonmissing data. Third, timing on adverse events on ECMO was not available, precluding more standard time-to-event analyses for the safety end points. We therefore calculated the incidence rate of adverse events on ECMO, making the conservative assumption that adverse events such as bleeding occurred once. This assumption, along with the exclusion of patients placed on ECMO with the intent of transplantation but not officially listed because of end-organ recovery that failed to occur, would, if anything, lead to an underestimate of the overall mortality and event rates compared with the real-world experience. Finally, data on HLA sensitization were not

### Table 4. Proposed Objective Performance Criteria for Extracorporeal Membrane Oxygenation as a Bridge to Heart Transplantation in Children (n=485)*

<table>
<thead>
<tr>
<th>Variables</th>
<th>Dilated Cardiomyopathy (n=135)</th>
<th>Myocarditis (n=51)</th>
<th>2 Ventricles (n=167)</th>
<th>1 Ventricle (n=132)</th>
<th>Overall (n=485)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy, bridge to transplantation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Survival to transplantation, %</td>
<td>55</td>
<td>39</td>
<td>37</td>
<td>39</td>
<td>43</td>
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<tr>
<td>Survival to recovery, %†</td>
<td>12</td>
<td>27</td>
<td>17</td>
<td>6</td>
<td>14</td>
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<tr>
<td>Survival to transplantation or recovery, %</td>
<td>67</td>
<td>67</td>
<td>54</td>
<td>45</td>
<td>57</td>
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<tr>
<td>Median ECMO duration, d</td>
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<td>10.4</td>
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</tr>
<tr>
<td>Efficacy, survival to discharge, %</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Survival to hospital discharge</td>
<td>63</td>
<td>59</td>
<td>44</td>
<td>33</td>
<td>48</td>
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<td>51</td>
<td>31</td>
<td>26</td>
<td>27</td>
<td>34</td>
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<tr>
<td>discharge</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Survival to hospital discharge if transplanted</td>
<td>93</td>
<td>80</td>
<td>71</td>
<td>67</td>
<td>79</td>
</tr>
<tr>
<td>Safety‡</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Serious adverse event rate§ (per day of ECMO)</td>
<td>0.15</td>
<td>0.13</td>
<td>0.19</td>
<td>0.17</td>
<td>0.17</td>
</tr>
<tr>
<td>Major adverse event rate</td>
<td>(per day of ECMO)</td>
<td>0.10</td>
<td>0.09</td>
<td>0.13</td>
<td>0.11</td>
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<tr>
<td>Neurological adverse events rate (per day of ECMO)</td>
<td>0.01</td>
<td>0.01</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
</tr>
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</table>

CHD indicates congenital heart disease; ECMO, extracorporeal membrane oxygenation.

*The objective performance goal cohort excludes 288 patients from the overall cohort with 1 or more of the following exclusion criteria: weight <3.0 or >50 kg, severe renal failure, total bilirubin >2.0, hypertrophic or restrictive cardiomyopathy, or brain death within 48 hours of ECMO cannulation.

†Recovery is defined as removed from the heart transplantation wait list as a result of clinical recovery.

‡The calculated rate describes the incidence of first adverse event only given that the Extracorporeal Life Support Organization (ELSO) does not capture recurrent adverse events.

§Serious adverse events as defined by the ELSO Registry (www.elso.med.umich.edu/registry).

<table>
<thead>
<tr>
<th>Time (days)</th>
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<tr>
<td>&lt; 1 mo</td>
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<tr>
<td>1 mo-1 yr</td>
</tr>
<tr>
<td>1 yr-18 yr</td>
</tr>
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</table>

**Figure 3.** Median support time on extracorporeal membrane oxygenation (ECMO) for the objective performance goal cohort vs median wait times for a donor organ. The median duration of ECMO support among those who died waiting is shown. Median waiting times for a donor organ were provided courtesy of the United Network for Organ Sharing.
Conclusions

We found that over a 15-year period in the United States, just half of all children supported with ECMO as a bridge to heart transplantation survived to hospital discharge. The risk of death varied by 2-fold based on patient factors. Patient factors predicting nonsurvival were cardiac diagnosis, renal dysfunction, and duration of ECMO >14 days. Era of ECMO support was not associated with outcome, suggesting that ECMO outcomes have been relatively constant over the past 2 decades. The objective performance estimates for ECMO described may be useful as clinical benchmarks for emerging mechanical circulatory support devices likely to supersedes ECMO in the next era of pediatric mechanical support.

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Disclosures

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References

Clinicall perspective

Extracorporeal membrane oxygenation (ECMO) has served for >2 decades as the standard of care for US children requiring mechanical support as a bridge to heart transplantation. Unfortunately, objective data on the safety and efficacy of ECMO for this purpose are limited in part because ECMO has never been approved by the Food and Drug Administration for this particular indication. In this study, data from the Extracorporeal Life Support Organization and Organ Procurement Transplant Network registries are combined to describe the efficacy and safety profile of ECMO for a bridge to heart transplantation and to propose objective performance goals that can be used as benchmarks to facilitate Food and Drug Administration approval of emerging miniaturized cardiac assist devices intended to replace ECMO. Among 733 children supported with ECMO as a bridge to heart transplantation since the mid-1990s, fewer than half survived to hospital discharge. Most deaths occurred while the children were on the wait list, but children successfully transplanted also had high posttransplantation mortality, accounting for up to one third of all in-hospital deaths. The risk of death was not uniform across all patient groups and varied by cardiac diagnosis, end-organ dysfunction, and duration of ECMO support. In the objective performance goal cohort, patients with cardiomyopathy had the highest survival to hospital discharge (63%), followed by patients with myocarditis (59%), 2-ventricle congenital heart disease (44%), and 1-ventricle congenital heart disease (33%). These findings suggest that, although ECMO may be effective for short-term circulatory support, it is not reliable for the long-term circulatory support necessary for children awaiting heart transplantation. Most important, these findings indicate that more effective modalities for long-term circulatory support are urgently needed for children.
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