

# Outcomes of Early Extracorporeal Membrane Oxygenation following the Norwood Procedure – Analysis of Consecutive Operations over 20 Years

**OBJECTIVE:** Extracorporeal membrane oxygenation (ECMO) is often required following infant cardiac surgery. We assessed if the severity of intraoperative residual lesions is associated with the need for ECMO postoperatively, and if early institution of ECMO improves in-hospital outcomes following the Norwood operation.

**METHODS:** This was a retrospective review of all patients who underwent the Norwood operation from 01/1997-11/2017 at a single institution. Previously published criteria were used to assign a residual lesion score (RLS) based on the intraoperative post-repair echocardiogram (class 1, no residua; class 2, minor residua; class 3, major residua requiring intraoperative revision) for all patients. In the primary analysis, associations between RLS and need for postoperative ECMO (primary outcome) were assessed with logistic regression, adjusting for age, prematurity, presence of non-cardiac anomalies or genetic syndromes, need for a second cardiopulmonary bypass (CPB) run, and any preoperative or procedure-specific risk factor (ascending aorta <2 mm, at least moderate atrioventricular valve regurgitation, aortic atresia, and intact atrial septum or obstructed pulmonary venous return). In the secondary analysis involving the subpopulation of patients who required ECMO, the association between early institution of ECMO (defined as ≤2 days following the index operation) and in-hospital mortality or transplant (secondary outcome) was similarly evaluated.

**RESULTS:** Of 500 patients who underwent the Norwood operation, 78 (15.6%) required ECMO postoperatively. There were 66 (13.2%) in-hospital deaths or transplants in the entire cohort. On univariable analysis, both RLS class 2 and 3 were significantly associated with the primary outcome (class 2: odds ratio [OR] 2.9, 95% confidence interval [CI] 1.2-7.2,  $p=0.023$ ; class 3: OR 27; 95% CI 7.9-89,  $p<0.001$ ). On multivariable analysis, RLS class 3 (OR 22, 95% CI 5.9-83,  $p<0.001$ ), prematurity (OR 3.1, 95% CI 1.5-6.8,  $p=0.004$ ), and need for a second CPB run (OR 4.5, 95% CI 2.1-9.8,  $p<0.001$ ) were significantly associated with postoperative ECMO (Table). Among patients who required ECMO following surgery, there were 44 (56.4%) deaths or transplants. Median time to ECMO was 1 day (interquartile range 0-5 days). On univariable analysis, early institution of ECMO resulted in a significantly reduced risk of in-hospital mortality or transplant (OR 0.13, 95% CI 0.037-0.48,  $p=0.002$ ). This finding was robust even after adjusting for RLS class and various patient- and procedure-related variables (Table).

**CONCLUSIONS:** Major intraoperative residual lesions are significantly associated with the need for ECMO following the Norwood operation. If mechanical circulatory support is required, early institution of ECMO, ideally within two postoperative days, may improve in-hospital transplant-free survival in this high-risk cohort.

| Postoperative ECMO<br>(Total Cohort, N = 500) |                  |         | In-Hospital Mortality or Transplant<br>(ECMO Subpopulation, N = 78) |         |
|---|------------------|---------|---|---------|
|   | OR (95% CI)      | P-Value | OR (95% CI)   | P-Value |
| Early ECMO <sup>1</sup>                       |                  |         | 0.13 (0.037, 0.48)  | 0.002   |
| RLS <sup>2</sup>                              |                  |         |   |         |
| Class 2                                       | 2.4 (0.94, 6.3)  | 0.067   | 2.7 (0.32, 23)  | 0.36    |
| Class 3                                       | 22 (5.9, 83)     | <0.001  | 8.5 (1.0, 72)   | 0.049   |
| Age <sup>3</sup>                              | 0.99 (0.92, 1.1) | 0.69    | 0.86 (0.75, 0.99)   | 0.040   |
| Premature                                     | 3.1 (1.5, 6.8)   | 0.004   | 2.4 (0.46, 13)  | 0.30    |
| Syndrome <sup>4</sup>                         | 1.5 (0.67, 3.2)  | 0.33    | 0.24 (0.039, 1.5)   | 0.12    |
| Preop Risk Factor <sup>5</sup>                | 0.50 (0.25, 1.0) | 0.055   | 1.3 (0.30, 5.9)   | 0.71    |
| Procedural Factors <sup>6</sup>               | 1.1 (0.60, 2.1)  | 0.74    | 1.2 (0.31, 4.3)   | 0.83    |
| 2 <sup>nd</sup> CPB Run                       | 4.5 (2.1, 9.8)   | <0.001  | 3.9 (0.78, 19)  | 0.096   |

**Table.** Multivariable predictors of need for postoperative ECMO (primary analysis) and in-hospital mortality or transplant (secondary analysis). <sup>1</sup>Defined as institution of ECMO within two postoperative days of the index operation, including initiation of ECMO in the operating room; <sup>2</sup>class 1 as baseline; <sup>3</sup>odds of each one day increase in age; <sup>4</sup>non-cardiac anomalies or genetic syndromes; <sup>5</sup>composite of preoperative mechanical ventilation, shock, cardiac arrest, ECMO, renal or hepatic failure, stroke or seizures, and sepsis; <sup>6</sup>procedural risk factors include ascending aorta <2 mm, at least moderate atrioventricular valve regurgitation, aortic atresia, intact atrial septum or obstructed pulmonary venous return, and previous intervention. CPB, cardiopulmonary bypass; CI, confidence interval; ECMO, extracorporeal membrane oxygenation; OR, odds ratio; RLS, residual lesion score.