# Textbook outcome for the Norwood operation—an informative quality metric in congenital heart surgery

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## ABSTRACT

**Objectives:** To develop a more holistic measure of center performance than operative mortality, we created a composite "textbook outcome" for the Norwood operation using several postoperative end points. We hypothesized that achieving the textbook outcome would have a positive prognostic and financial impact.

**Methods:** This was a single-center retrospective study of primary Norwood operations from 2005 to 2021. Through interdisciplinary clinician consensus, textbook outcome was defined as freedom from operative mortality, open or catheterbased reintervention, 30-day readmission, extracorporeal membrane oxygenation, cardiac arrest, reintubation, length of stay >75%ile from Society of Thoracic Surgeons data report (66 days), and mechanical ventilation duration >75%ile (10 days). Multivariable logistic regression and Cox proportional hazards modeling were used to determine predictive factors for textbook outcome achievement and association of the outcome with long-term survival, respectively.

**Results:** Overall, 30% (58/196) of patients met the textbook outcome. Common reasons for failure to attain textbook outcome were prolonged ventilation (68/138, 49%) and reintubation (63/138, 46%). In multivariable analysis, greater weight (odds ratio [OR], 2.11; 95% confidence interval [CI], 1.17-3.95; P = .02) was associated with achieving the textbook outcome whereas preoperative shock (OR, 0.36; 95% CI, 0.13-0.87; P = .03) and longer bypass time (OR, 0.99; 95% CI, 0.98-1.00; P = .002) were negatively associated. Patients who met the outcome incurred fewer hospital costs (\$152,430 [141,798-177,983] vs \$269,070 [212,451-372,693], P < .001), and after adjusting for patient factors, achieving textbook outcome was independently associated with decreased risk of all-cause mortality (hazard ratio, 0.45; 95% CI, 0.22-0.89; P = .02).

**Conclusions:** Outcomes continue to improve within congenital heart surgery, making operative mortality a less-sensitive metric. The Norwood textbook outcome may represent a balanced measure of a successful episode of care. (JTCVS Open 2023;15:394-405)

Traditionally, congenital heart surgery centers have been evaluated almost exclusively on operative mortality.<sup>1</sup> However, this is an imperfect metric in the current era. As outcomes continue to improve, shareholders such as referring physicians, patients, families, and payers will benefit from



## nents of the Norwood textbook outcome.

#### CENTRAL MESSAGE

1.00

0.25

The Norwood textbook outcome is a holistic, binary, composite quality measure that may better represent a successful episode of care after the operation.

#### PERSPECTIVE

Outcomes continue to improve within congenital heart surgery, making operative mortality a lesssensitive metric of quality. Textbook outcomes are operation-specific composite quality metrics that are developed by interdisciplinary clinician consensus. Achievement of these balanced outcomes correlate with cost of care and longterm prognosis.

more information on which centers are providing safe, value-based, holistic surgical care.

One solution is to develop composite quality measures, accounting for both mortality and morbidity end points, to provide insight into congenital heart center performance.

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## **Abbreviations and Acronyms**

- CI = confidence interval
- HLHS = hypoplastic left heart syndrome
- HR = hazard ratio
- OR = odds ratio

An example is the textbook outcome, which is a composite measure based on multiple postoperative end points that, when achieved, represents the ideal "textbook" hospitalization after a certain operation.<sup>2-6</sup> In complex operations such as lung transplantation, achievement of the textbook outcome has been shown to predict longer survival as well as decreased costs.<sup>3</sup> However, composite quality measures in congenital heart surgery are still early in development.<sup>7-9</sup>

The Norwood operation is one of the most challenging in congenital heart surgery, with overall operative mortality of approximately 15%, complication rates greater than 75%, and large variation in outcomes between centers.<sup>10-12</sup> Thus, construction of an operation-specific textbook outcome for the Norwood operation may be particularly informative. Here, we aimed to define a textbook outcome for the Norwood operation and evaluated its ability to predict long-term outcomes and cost of care. We hypothesized that development of a Norwood textbook outcome could serve as a quality-improvement tool and identify high-value care. In addition, we aimed to develop a nomogram for prognostication and family counseling purposes that predicts the likelihood of textbook outcome achievement, given patient risk factors.

## **METHODS**

This study received approval from the institutional review board (Pro00101549, January 2019), and the need for individual patient consent was waived due to the retrospective nature of the study.

## **Cohort Selection and Data Acquisition**

This was a retrospective study of patients who underwent the Norwood operation from 2005 to 2021 at our institution. Patients who underwent previous pulmonary artery banding or the hybrid Norwood operation were excluded, yielding a final cohort of primary Norwood patients. Demographics and perioperative variables were extracted from our prospectively maintained single-ventricle database.<sup>13</sup> Immediate preoperative echocardiogram reports were collected. Total, direct, and indirect costs accrued during the index hospital admission were provided by the financial sector of the medical center. Direct costs are defined as costs that are directly attributed to patient care, such as nursing services, supplies, medications, imaging studies, and laboratory tests. Indirect costs are those that are not directly related to patient care, such as administration, information technology, health records, and maintenance.

## **Textbook Outcome Definition**

An interdisciplinary group of clinicians composed of 2 staff surgeons, 2 pediatric cardiologists, and 1 pediatric intensivist collaborated to define potential indicators of quality and success after the Norwood operation. This

set of indicator variables was then narrowed to those thought to be reliably captured in the Society of Thoracic Surgeons National Database. The final textbook outcome for the Norwood operation was defined as postoperative freedom from the following: operative mortality, cardiac reintervention before discharge, readmission within 30 days of hospital discharge, extracorporeal membrane oxygenation before discharge, cardiac arrest before discharge, reintubation before discharge, total length of stay >75th percentile (66 days), and prolonged invasive mechanical ventilation duration >75th percentile (10 days) (Table 1). Operative mortality was defined as death during the acute episode of care in which the operation was performed or within 30 days of the operation and was included in the textbook outcome definition for 2 reasons. First, because the expected mortality after the Norwood operation is approximately 15%, excluding the patients who died would not make for an accurate analysis of program quality. Second, if operative mortality was not included, a patient who died postoperatively but experienced none of the other counted complications could theoretically be recorded as having achieved the textbook outcome. Cardiac reintervention was defined as open or catheter-based intervention after the Norwood operation, including mediastinal exploration for bleeding but excluding planned delayed sternal closure. Like previous textbook outcome reports, 75th percentile cutoffs were used for continuous end points.<sup>3,14</sup> These values were defined using the 2021 Society of Thoracic Surgeons Data Report rather than institutional statistics to reduce bias. Other postoperative outcomes such as neurologic injury or renal failure requiring dialysis were considered but not included in the textbook outcome definition, given inconsistent and subjective reporting as well as low occurrence rates in our cohort. In addition, patients in our cohort who suffered clinically significant neurologic injury or renal failure did not achieve the textbook outcome anyway due to their experiencing a different complication that was counted within the outcome.

## **Statistical Analysis**

Descriptive statistics and hypothesis testing were used to compare baseline characteristics, end points, and costs of patients who achieved and did not achieve the textbook outcome. The overall cohort consisted of all patients received Norwood operations. A subgroup analysis was performed for patients specifically with hypoplastic left heart syndrome (HLHS). Continuous data are presented as mean  $\pm$  standard deviation or median (interquartile range) depending on normality, which was assessed using the Shapiro–Wilk test.

Univariable and multivariable logistic regression using the "logit" model was used to determine factors associated with Norwood textbook outcome achievement. For the multivariable analysis, covariates were selected from those listed in Table 2 using backwards stepwise regression. Model discrimination was assessed using the bias-corrected c-statistic with 95% confidence intervals (CIs) determined based on N = 500 bootstrapped resamples (sampling with replacement). A nomogram was constructed with the final multivariable model for use in patient prognostication as previously described.<sup>2,15</sup> Kaplan–Meier analysis was used to compare postoperative survival stratified by achievement of the Norwood textbook outcome. After verifying the proportional hazards assumption, univariable and multivariable Cox proportional hazards models were developed to assess the association of textbook outcome achievement, as well as other a priori selected covariates, with survival (Table E1).<sup>10</sup> All analyses were performed using R, version 4.1.2 (R Foundation for Statistical Computing).

## RESULTS

## **Overall Results**

In total, 196 patients who underwent a Norwood operation were included, 30% (58/196) of whom achieved the textbook outcome (Figure 1). Patients who achieved the textbook outcome were younger at time of the operation

TABLE 1. Definition of textbook outcome after the Norwood operation

1. No operative mortality
2. No unplanned open or catheter-based reintervention before discharge
3. No readmission within 30 d of hospital discharge
4. No extracorporeal membrane oxygenation before discharge
5. No postoperative cardiac arrest before discharge
6. No postoperative reintubation before discharge
7. Total length of stay <75% ile from STS Data Report (66 d)
<ol> <li>8. Total mechanical ventilation duration &lt;75% ile from STS Data Report (10 d)</li> </ol>

STS, Society of Thoracic Surgeons.

and had greater weight, decreased prevalence of preoperative ventilation and shock, and shorter cardiopulmonary bypass times (Table 2). Of the 138 patients who did not achieve textbook outcome, the most common reasons for failure were related to mechanical ventilation, including prolonged mechanical ventilation (49%, 68/138), and reintubation (46%, 63/138), as well as prolonged length of stay (30%, 41/138). Most patients who did not achieve the outcome had 1 (34%, 47/138) or 2 (26%, 36/138) of the 8 postoperative complications considered (Figure E1).

## Predictive Factors for Textbook Outcome Achievement

In univariable analysis, greater birth weight (odds ratio [OR], 2.03; 95% CI, 1.18-3.61; P = .01) was associated with achieving textbook outcome, whereas preoperative shock (OR, 0.36; 95% CI, 0.13-0.87; P = .03) and longer cardiopulmonary bypass time (OR, 0.99; 95% CI, 0.98-1.00; P = .002) were negatively associated. After adjustment in a multivariable model, the same factors were found to be independently associated with the textbook outcome: greater weight (OR, 2.11; 95% CI, 1.17-3.95; P = .02) was positively associated, whereas preoperative shock (OR, 0.36; 95% CI, 0.13-0.87; P = .03) and longer cardiopulmonary bypass time (OR, 0.99; 95% CI, 0.98-1.00; P = .002) were negatively associated. The variable moderate-severe

TABLE 2. B	aseline patient	characteristics	and operative details
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	Achieved textbook	Failed textbook	
Characteristic	outcome (n = 58)	outcome (n = 138)	P value
Demographics			
Male, N (%)	31 (53%)	80 (58%)	.60
Age, d, surgery	4 (3-7)	6 (4-8)	.01
Prematurity,* N (%)	3 (5%)	18 (13%)	.10
Weight, kg	3.4 (3.0-3.6)	3.1 (2.8-3.5)	.005
Genetic syndrome or chromosomal abnormality, N (%)	10 (17%)	32 (23%)	.40
Diagnosis and imaging			
Anatomical diagnosis, N (%)			>.99†
HLHS	39 (67%)	89 (64%)	
uAVCD	5 (9%)	17 (12%)	
AA/AS	5 (9%)	12 (9%)	
DILV	4 (7%)	8 (6%)	
DORV	3 (5%)	7 (5%)	
Tricuspid atresia	1 (2%)	4 (3%)	
Other	1 (2%)	1 (1%)	
Right ventricular dominance, N (%)	48 (83%)	112 (81%)	.80
Moderate-severe systemic AV valve regurgitation, N (%)	2 (3%)	18 (13%)	.04
Moderate-severe ventricular dysfunction, N (%)	3 (5%)	1 (1%)	.08
Restrictive interatrial septum, N (%)‡	8 (14%)	26 (19%)	.40
Obstructed anomalous pulmonary venous return, N (%)	0 (0%)	5 (4%)	.30
Preoperative status			
Preoperative shock, N (%)	7 (12%)	35 (25%)	.04
Preoperative ventilator, N (%)	17 (29%)	60 (43%)	.06
Preoperative NEC, N (%)	1 (2%)	5 (4%)	.70
Preoperative stroke or seizure, N (%)	3 (5%)	10 (7%)	.80
Operative details			
Cardiopulmonary bypass time, mins	160 (148-182)	177 (157-217)	.002
Blalock-Taussig shunt, N (%)	9 (16%)	14 (10%)	.30

*HLHS*, Hypoplastic left heart syndrome; *uAVCD*, unbalanced atrioventricular canal defect; *AA*, aortic atresia; *AS*, aortic stenosis; *DILV*, double-inlet left ventricle; *DORV*, double-outlet right ventricle; *AV*, atrioventricular; *NEC*, necrotizing enterocolitis. Bold values indicate P < .05. \*Gestational age <37 wk.  $\dagger \chi^2$ .  $\ddagger$ Restrictive interatrial septum was defined as a mean gradient >10 mm Hg.

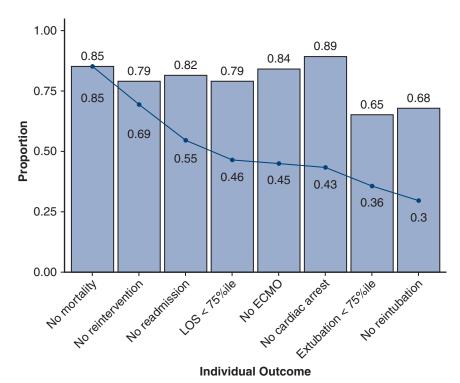


FIGURE 1. Patient proportion that met individual postoperative outcomes that compose the textbook outcome (*above bar*) and proportion that cumulatively met each successive outcome (*below line*). LOS, Length of stay; ECMO, extracorporeal membrane oxygenation.

atrioventricular valve regurgitation was retained in the multivariable model through variable selection but was not statistically significant (OR, 0.24; 95% CI, 0.04-0.99; P = .08) (Table 3). The bias-corrected c-statistic and 95% CI of the model was 0.74 (95% CI, 0.65-0.80).

Figure 2 shows a nomogram for the prediction of probability of achieving the Norwood textbook outcome. To illustrate, a patient weighing 2.75 kg (20 points), without preoperative shock (20 points), without atrioventricular valve regurgitation (30 points), and with 180 minutes of

TABLE 3. Univariable and multivariable logistic regression to predict textbook outcome a	achievement for the Norwood operation
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	Univariate analysis		Multivariable a	analysis
N = 196 Norwood patients	OR (95% CI)	P value	OR (95% CI)	P value
Age, d	0.99 (0.94-1.03)	.70		
Weight, kg	2.03 (1.18-3.61)	.01	2.11 (1.17-3.95)	.02
Gender male	0.83 (0.45-1.55)	.60		
Syndromic or chromosomal abnormality	0.69 (0.30-1.48)	.40		
Prematurity	0.36 (0.08-1.13)	.12		
Preoperative neurologic deficit	0.70 (0.15-2.39)	.60		
Preoperative necrotizing enterocolitis	0.47 (0.02-2.98)	.50		
Preoperative ventilator	0.54 (0.27-1.03)	.07		
Preoperative shock	0.40 (0.16-0.92)	.04	0.36 (0.13-0.87)	.03
Right ventricular dominance	1.11 (0.51-2.59)	.80		
Moderate-severe AV regurgitation	0.24 (0.04-0.86)	.06	0.24 (0.04-0.99)	.08
Moderate-severe ventricular dysfunction	7.47 (0.93-153)	.08		
Restrictive interatrial septum	0.69 (0.28-1.57)	.40		
CPB time (per min)	0.99 (0.98-1.00)	.002	0.99 (0.98-1.00)	.002
BT shunt	1.63 (0.64-3.96)	.30		

OR, Odds ratio; CI, confidence interval; AV, atrioventricular; CPB, cardiopulmonary bypass; BT, Blalock-Taussig. Bold values indicate P < .05.

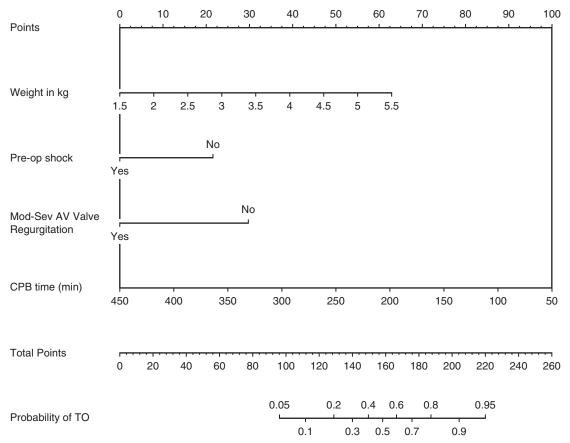


FIGURE 2. Nomogram for the prediction of likelihood of achieving a textbook outcome (*TO*) after the Norwood operation. Bias-corrected c-statistic 0.74 (95% CI 0.65-0.80). *AV*, Atrioventricular; *CPB*, cardiopulmonary bypass.

cardiopulmonary bypass (70 points) would have 140 points, which corresponds to a roughly 30% probability of achieving the outcome.

## **Subgroup Analysis of HLHS**

To assess whether textbook outcome analysis would be informative in a more homogeneous cohort, a subgroup analysis of patients born with HLHS was performed. A total of 30% (39/128) patients with HLHS achieved the textbook outcome (Figure E2). Patients with HLHS who achieved the textbook outcome weighed more at surgery, had lower prevalence of preoperative shock, and lower cardiopulmonary bypass times but had comparable anatomic findings at birth (Table E2). In multivariable analysis, greater weight was positively associated with textbook outcome achievement whereas the presence of a genetic syndrome or chromosomal abnormality, preoperative ventilation or shock, and longer cardiopulmonary bypass times were negatively associated with outcome achievement (Table E3).

## **Financial Outcome**

Patients who achieved the Norwood textbook outcome incurred lower total hospital costs than patients who did

not (\$152,430 [141,798-177,983] vs \$269,070 [212,451-372,693], P < .001). In subdividing total costs, patients that achieved the outcome incurred lower direct and indirect costs (Figure 3).

## Long-Term Survival

Kaplan–Meier analysis demonstrated a difference in survival for patients who achieved the Norwood textbook outcome (5-year survival: 76.1% [64.2-90.1] vs 57.2% [48.5-67.5], log-rank P = .005) (Figure 4). In a multivariable Cox proportional hazards model, achieving the Norwood textbook outcome was found to be an independent positive prognostic factor (hazard ratio [HR], 0.45; 95% CI, 0.22-0.89; P = .02), whereas having a chromosomal abnormality or genetic syndrome (HR 2.05; 95% CI, 1.11-3.79; P = .02), right ventricular dominance (HR 4.34; 95% CI, 1.53-12.3; P = .006), or moderate-severe ventricular dysfunction (HR 4.27; 95% CI, 1.08-16.9; P = .04) were poor prognostic factors.

## COMMENT

Composite outcomes may offer new insights into the quality and value of care provided by congenital heart

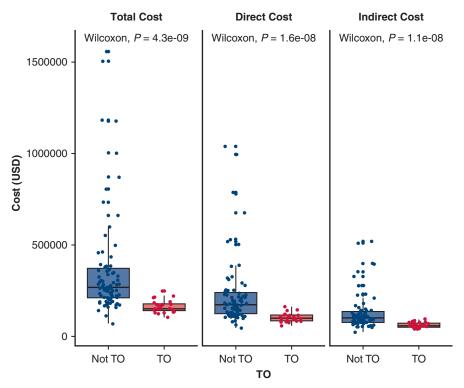


FIGURE 3. Box-and-whisker plot demonstrating the total cost of hospital admission for patients who achieved versus did not achieve the Norwood textbook outcome. Cost is then displayed subdivided into total direct and total indirect costs. *TO*, Textbook outcome.

surgery programs. Here, we aimed to define a composite "textbook" outcome for the Norwood operation. First, we found that 30% of patients in the study cohort achieved the textbook outcome and determined that mechanical ventilation complications and prolonged length of stay were the most common reasons for not achieving the outcome. Second, we developed a nomogram with moderate prognostic ability to predict the likelihood of a patient achieving the textbook outcome. Third, we found that achieving the outcome was an independent positive predictor of long-term survival while controlling for patient risk factors. Lastly, we found that achievement of textbook outcome correlated with lower hospital costs.

In the modern era, evaluating congenital heart surgery programs is difficult. Centers have traditionally been evaluated on operative mortality, but survival is improving and converging nationally for all congenital index operations.<sup>16</sup> Furthermore, operative mortality is a one-dimensional metric that does not provide a detailed overview of perioperative performance. An alternate approach is to analyze multiple individual outcomes in parallel, such as survival, length of stay, and ventilator duration, but this greatly increases the amount of data required to understand performance. Composite outcomes provide a balance between these methods and combine multiple indicators into summary scores to provide holistic information. Such metrics carry benefit for multiple groups, such as families deciding

which center to take their children, program administrators benchmarking performance, and payers negotiating valuebased payments. Composite outcomes have been posited in cardiac surgery but these have been for academic purpose and are not widely employed.<sup>9,17,18</sup>

Textbook outcome analysis may be a solution. Recently, textbook outcome analysis has emerged as a composite quality metric based on the achievement of multiple postoperative mortality and morbidity end points. Previous singlecenter studies in organ transplantation, lung cancer surgery, and other operations have found textbook outcome rates ranging from 24% to 44%, which is close to our Norwood rate.<sup>3,4,14</sup> There are many advantages to this analysis methodology. For one, these outcomes can be developed using standardized perioperative variables reported in national outcomes databases. Textbook outcome analysis also provides a more effective method to differentiate center performance. In multi-institutional analyses, case-mix-adjusted textbook outcome rates varied significantly between centers, which highlights its discriminative power.<sup>2,5,6,19</sup> Second, careful review of composite outcome rates by center leadership can drive targeted quality improvement efforts, motivated by the fact that textbook outcome achievement independently predicts long-term survival. Third, predictive analyses of textbook outcomes with nomograms can provide patient-level prognostication.<sup>15</sup> Lastly, as mortality and morbidity continue to improve,

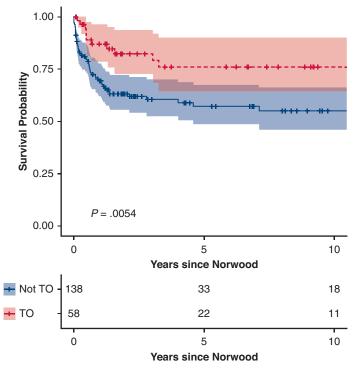


FIGURE 4. Unadjusted Kaplan–Meier curves for survival stratified by achievement of Norwood textbook outcome. *P* value by log-rank test. 95% CI. *TO*, Textbook outcome.

cost of care stands as the next target for quality improvement.<sup>20</sup> Indeed, some groups have found correlations between textbook outcomes and lower hospitalization costs.<sup>3,4,14</sup> As these costs are not publicly reported, analysis of textbook outcome rates may provide insight into which centers are providing high-value care.

The Norwood operation may be the ideal starting point for textbook outcome analysis in congenital heart surgery. Although the operation has seen recent advancements in perfusion strategy and perioperative care,<sup>21-26</sup> it is still technically complex, with high intercenter variation in outcome and cost.<sup>10,11</sup> Like other reports, we developed this composite outcome by assembling an interdisciplinary team of cardiac surgeons, cardiologists, and intensivists who decided which outcomes are the most impactful during recovery. Each of the chosen end points also has been shown to individually correlate with clinically relevant outcomes after Norwood.<sup>27-31</sup> Regarding the continuous end points that constitute the textbook outcome, we elected to use the 75th percentile values from the most recent data report from the Society of Thoracic Surgeons. Although previous reports have used either arbitrary cutoffs or institutional 75th percentile values, there is variability in intensive care unit practices across centers and using national statistics may therefore be more objective.<sup>32</sup>

Textbook outcome analysis can identify qualityimprovement opportunities. The rate of textbook outcome achievement in our Norwood cohort was 30%, which is

similar to the rate of outcome achievement in other complex operations.<sup>3,4</sup> Although 30% may seem high, there is no comparison point at present and an alternate interpretation is that 70% of patients had a "complicated" postoperative course. Of note, this figure is consistent with the 78% postoperative complication rate identified after Norwood in the Single Ventricle Reconstruction trial.<sup>33</sup> One way to begin quality-improvement initiatives using textbook outcomes is to analyze the individual components of the outcome. We found that the most common reasons for failing to achieve the outcome at our institution were related to mechanical ventilation and prolonged length of stay. These results have spawned discussions at our center to develop standardized postoperative care protocols, which at other centers have reduced intensive care unit length of stay and ventilation duration after Norwood.34

Textbook outcome analysis can also provide patientcentered prognostication. In this study, several factors influenced the probability of achieving the Norwood textbook outcome. These included weight at surgery, preoperative shock, moderate-severe atrioventricular valve regurgitation, and cardiopulmonary bypass time, all of which are known to associate with outcomes after the Norwood operation.<sup>10</sup> Using these data, a nomogram was developed for patient prognostication. Internal validation with bootstrapping revealed moderate prognostic ability of the model with a c-statistic of 0.74 (95% CI, 0.65-0.80). This tool may enable preoperative risk assessment and the allocation of resources to patients who have lower likelihood of outcome achievement. Although risk scores have been developed for mortality after Norwood,<sup>35</sup> the textbook outcome nomogram predicts the composite probability for mortality *or* a complicated postoperative course. This could be more meaningful to patients and their families, who may experience complications as "all-or-none" events regardless of type.<sup>2,3</sup>

Analysis of textbook outcome achievement can also identify high-value care. The Norwood operation is associated with high use of resources.<sup>36</sup> Strikingly, analysis of data from the Single Ventricle Reconstruction trial demonstrated up to 5-fold variability in the mean cost of Norwood operations between enrolled centers.<sup>12</sup> A majority of this cost was explained by differences in complication rates, such as prolonged pleural effusion, seizure, and wound infection, which were more frequently observed at high-cost centers. In addition, the Norwood operation may represent the greatest opportunity for cost reduction of any index congenital procedure.<sup>36</sup> In our study, we found that achievement of the Norwood textbook outcome was associated with nearly 50% lower total hospital costs. This finding could be driven primarily by shorter length of stay in patients who achieved the outcome, but mechanical circulatory support and reinterventions also carry substantial costs.<sup>36,37</sup> Although hospital costs are not collected in national databases, it is reasonable to assume that the relationship we found in our study holds at other centers. Therefore, rates of textbook outcome achievement can be used as a surrogate for shareholders to identify centers providing high-value care.

Lastly, textbook outcome analysis may inform regionalization efforts within congenital heart surgery. Simulations have shown that regionalizing patients to high-volume centers may reduce mortality with minimum additional distraveled.<sup>38</sup> However, the volume-outcomes tance relationship is not straightforward. In fact, for the Norwood operation, center volume explains only 15% of the between-center outcome variation.<sup>39</sup> Indeed, all larger programs do not perform better than all smaller programs, and there may be centers that do fewer cases but do those cases better.<sup>40</sup> We propose that textbook outcome rates can be used for this purpose as a more holistic indicator of program performance independent of the bias associated with center reputation. To allow for meaningful comparison between centers, however, risk adjustment will have to be performed to control for differences in patient cohorts and case-mix between centers that may affect rates of textbook outcome achievement. For instance, a center that performs more Norwood procedures on high-risk patients (ie, smaller and sicker children) may have a lower absolute textbook outcome achievement rate, but this would be expected. Ideally, multi-institutional analyses will allow for the generation of observed-to-expected ratios of Norwood textbook outcome rates for each participating center. Furthermore, using the nomogram concept, calculating differences in

textbook outcome achievement between centers specifically for the greatest-risk patient subgroups may identify differences in nuances and quality of care. After risk adjustment is performed, future study examining the "volume– textbook outcomes" relationship on a national scale would surely be of interest. Perhaps there is a critical number of textbook outcomes, or sequential successful outcomes achieved per year, for specific operations that indicates that a program is "high-performing."

## Limitations

First, this is a retrospective single-center study, and there may be unmeasured confounders. Second, the presence of a chromosomal abnormality or genetic syndrome was a broad definition that included patients with heterogeneous diagnoses including trisomy 21, DiGeorge syndrome, heterotaxy, and others. These patient groups were not studied individually due to sample size limitations. Third, the Norwood textbook outcome is not a weighted metric. That is, all postoperative end points are treated equally, and failure to meet any one of them is considered a failure to achieve textbook outcome. As other reports discuss, this "all-ornothing" metric may be justified by the fact that textbook outcome failure is a sensitive marker of a complicated postoperative course.<sup>2</sup> Fourth, the Norwood textbook outcome was developed at one institution, which may decrease generalizability. However, the specific end points that make up these outcomes are subject to modification through academic discussion.

## **CONCLUSIONS**

This study demonstrates the development of an informative composite outcome for the Norwood operation. We show that achievement of the Norwood textbook outcome correlates with lower cost of care and better long-term prognosis. Future analysis of adjusted textbook outcome rates across centers may enable the congenital heart surgery community to provide better care by continuing efforts in quality improvement and regionalization.

## **Conflict of Interest Statement**

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

#### References

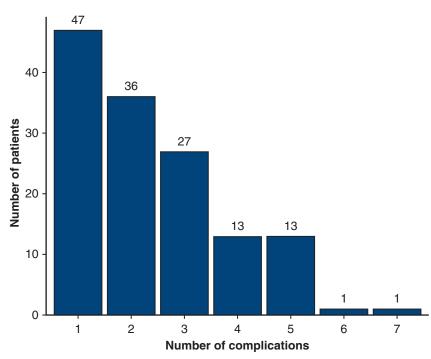
- Jacobs JP, Mayer JE Jr, Pasquali SK, Hill KD, Overman DM, St Louis JD, et al. The Society of Thoracic Surgeons Congenital Heart Surgery database: 2019 update on outcomes and quality. *Ann Thorac Surg.* 2019;107:691-704.
- Merath K, Chen Q, Bagante F, Alexandrescu S, Marques HP, Aldrighetti L, et al. A multi-institutional international analysis of textbook outcomes among patients

undergoing curative-intent resection of intrahepatic cholangiocarcinoma. JAMA Surg. 2019;154:e190571.

- Halpern SE, Moris D, Gloria JN, Shaw BI, Haney JC, Klapper JA, et al. Textbook outcome: definition and analysis of a novel quality measure in lung transplantation. *Ann Surg.* 2023;277:350-7.
- 4. Moris D, Shaw BI, Gloria J, Kesseli SJ, Samoylova ML, Schmitz R, et al. Textbook outcomes in liver transplantation. *World J Surg.* 2020;44:3470-7.
- Ten Berge MG, Beck N, Steup WH, Verhagen A, van Brakel TJ, Schreurs WH, et al. Textbook outcome as a composite outcome measure in non–small-cell lung cancer surgery. *Eur J Cardio Thorac Surg.* 2021;59:92-9.
- Krischak MK, Au S, Halpern SE, Olaso DG, Moris D, Snyder LD, et al. Textbook surgical outcome in lung transplantation: analysis of a US national registry. *Clin Transplant*. 2022;36:e14588.
- Pasquali SK, Shahian DM, O'Brien SM, Jacobs ML, Gaynor JW, Romano JC, et al. Development of a congenital heart surgery composite quality metric: part 1—conceptual framework. *Ann Thorac Surg.* 2019;107:583-9.
- O'Brien SM, Jacobs JP, Shahian DM, Jacobs ML, Gaynor JW, Romano JC, et al. Development of a congenital heart surgery composite quality metric: part 2—analytic methods. *Ann Thorac Surg.* 2019;107:590-6.
- 9. Gardner MM, Keim G, Hsia J, Mai AD, William Gaynor J, Glatz AC, et al. Characterization of "ICU-30": a binary composite outcome for neonates with critical congenital heart Disease. *J Am Heart Assoc*. 2022;11:e025494.
- Hornik CP, He X, Jacobs JP, Li JS, Jaquiss RD, Jacobs ML, et al. Complications after the Norwood operation: an analysis of the Society of Thoracic Surgeons Congenital Heart Surgery database. *Ann Thorac Surg.* 2011;92:1734-40.
- 11. Jacobs JP, O'Brien SM, Pasquali SK, Jacobs ML, Lacour-Gayet FG, Tchervenkov CI, et al. Variation in outcomes for benchmark operations: an analysis of the Society of Thoracic Surgeons Congenital Heart Surgery database. *Ann Thorac Surg.* 2011;92:2184-91; discussion 2191-2.
- McHugh KE, Pasquali SK, Hall MA, Scheurer MA. Cost variation across centers for the Norwood operation. *Ann Thorac Surg.* 2018;105:851-6.
- Zhu A, Meza JM, Prabhu NK, McCrary AW, Allareddy V, Turek JW, et al. Survival after intervention for single-ventricle heart disease over 15 years at a single institution. *Ann Thorac Surg.* 2022;114:2303-12.
- Halpern SE, Moris D, Shaw BI, Kesseli SJ, Samoylova ML, Manook M, et al. Definition and analysis of textbook outcome: a novel quality measure in kidney transplantation. *World J Surg.* 2021;45:1504-13.
- 15. Zhang Z, Kattan MW. Drawing Nomograms with R: applications to categorical outcome and survival data. *Ann Transl Med.* 2017;5:211.
- 16. Jacobs JP, He X, Mayer JE Jr, Austin EH III, Quintessenza JA, Karl TR, et al. Mortality trends in pediatric and congenital heart surgery: an analysis of the Society of Thoracic Surgeons Congenital Heart Surgery database. *Ann Thorac Surg.* 2016;102:1345-52.
- Stoppe C, McDonald B, Benstoem C, Elke G, Meybohm P, Whitlock R, et al. Evaluation of persistent organ dysfunction plus death as a novel composite outcome in cardiac surgical patients. *J Cardiothorac Vasc Anesth.* 2016;30:30-8.
- Butts RJ, Scheurer MA, Zyblewski SC, Wahlquist AE, Nietert PJ, Bradley SM, et al. A composite outcome for neonatal cardiac surgery research. *J Thorac Cardiovasc Surg.* 2014;147:428-33.
- Görgec B, Benedetti Cacciaguerra A, Lanari J, Russolillo N, Cipriani F, Aghayan D, et al. Assessment of textbook outcome in laparoscopic and open liver surgery. JAMA Surg. 2021;156:e212064.
- Nellis JR, Prabhu NK, Hoover AC, Muller MJ, Overbey DM, Chen EP, et al. Understanding and managing direct operating room supply costs in cardiac surgery. *Ann Thorac Surg.* 2023;115:1520-5.
- Prabhu NK, Nellis JR, Meza JM, Benkert AR, Zhu A, McCrary AW, et al. Sustained Total All-Region perfusion during the Norwood operation and postoperative recovery. *Semin Thorac Cardiovasc Surg.* 2023;35:140-7.
- Andersen ND, Prabhu NK, Turek JW. Sustained Total All-Region (STAR) perfusion for Norwood reconstruction. *Operat Tech Thorac Cardiovasc Surg.* 2020;25: 126-39.

- Prabhu NK, Turek JW, Andersen ND. Sustained Total All-Region (STAR) perfusion for Norwood reconstruction with complex intracardiac repair. *Perfusion*. 2021;36:532-4.
- Siffring T, Prabhu N, Smigla G, Kaemmer D. In vitro evaluation of flow distribution in all-region perfusion during the Norwood operation. *J Extra Corpor Tech*nol. 2020;52:261-5.
- 25. Siffring T, Prabhu N, Evans A, Dauch W, Smigla G, Kaemmer D. Sustained Total All-Region (STAR) perfusion: an optimized perfusion strategy for Norwood reconstruction. *J Extra Corpor Technol.* 2020;52:332-6.
- **26.** Turek JW, Hanfland RA, Davenport TL, Torres JE, Duffey DA, Patel SS, et al. Norwood reconstruction using continuous coronary perfusion: a safe and translatable technique. *Ann Thorac Surg.* 2013;96:219-24.
- Sengupta A, Gauvreau K, Kaza A, Hoganson D, del Nido PJ, Nathan M. Timing of reintervention influences survival and resource utilization following first-stage palliation of single ventricle heart disease. *J Thorac Cardiovasc Surg.* 2022;165: 436-46.
- Mackie AS, Gauvreau K, Newburger JW, Mayer JE, Erickson LC. Risk factors for readmission after neonatal cardiac surgery. *Ann Thorac Surg.* 2004;78: 1972-8; discussion 1978.
- Friedland-Little JM, Hirsch-Romano JC, Yu S, Donohue JE, Canada CE, Soraya P, et al. Risk factors for requiring extracorporeal membrane oxygenation support after a Norwood operation. *J Thorac Cardiovasc Surg.* 2014;148:266-72.
- Mastropietro CW, Cashen K, Grimaldi LM, Narayana Gowda KM, Piggott KD, Wilhelm M, et al. Extubation failure after neonatal cardiac surgery: a multicenter analysis. J Pediatr. 2017;182:190-6.e4.
- 31. Tabbutt S, Ghanayem N, Ravishankar C, Sleeper LA, Cooper DS, Frank DU, et al. Risk factors for hospital morbidity and mortality after the Norwood procedure: a report from the Pediatric Heart Network Single Ventricle Reconstruction trial. *J Thorac Cardiovasc Surg.* 2012;144:882-95.
- Pasquali SK, Ohye RG, Lu M, Kaltman J, Caldarone CA, Pizarro C, et al. Variation in perioperative care across centers for infants undergoing the Norwood procedure. J Thorac Cardiovasc Surg. 2012;144:915-21.
- 33. Ohye RG, Sleeper LA, Mahony L, Newburger JW, Pearson GD, Lu M, et al. Comparison of shunt types in the Norwood procedure for single-ventricle lesions. *N Engl J Med.* 2010;362:1980-92.
- 34. Natarajan SS, Stagg A, Taylor AM, Griffis HM, Bosler CK, Cates M, et al. Standardization of the perioperative management for neonates undergoing the Norwood operation for hypoplastic left heart syndrome and related heart defects. *Pediatr Crit Care Med*. 2020;21:e848–e857.
- Gupta P, Chakraborty A, Gossett JM, Rettiganti M. A prognostic tool to predict outcomes in children undergoing the Norwood operation. *J Thorac Cardiovasc* Surg. 2017;154:2030-7.e2032.
- 36. Pasquali SK, He X, Jacobs ML, Shah SS, Peterson ED, Gaies MG, et al. Excess costs associated with complications and prolonged length of stay after congenital heart surgery. *Ann Thorac Surg.* 2014;98:1660-6.
- Hansen JE, Madsen NL, Bishop L, Morales DLS, Anderson JB. Longitudinal health care cost in hypoplastic left heart syndrome palliation. *Pediatr Cardiol*. 2018;39:1210-5.
- Welke KF, Pasquali SK, Lin P, Backer CL, Overman DM, Romano JC, et al. Regionalization of congenital heart surgery in the United States. *Semin Thorac Cardiovasc Surg.* 2020;32:128-37.
- 39. Pasquali SK, Jacobs JP, He X, Hornik CP, Jaquiss RD, Jacobs ML, et al. The complex relationship between center volume and outcome in patients undergoing the Norwood operation. *Ann Thorac Surg.* 2012;93:1556-62.
- Kalfa D, Chai P, Bacha E. Surgical volume-to-outcome relationship and monitoring of technical performance in pediatric cardiac surgery. *Pediatr Cardiol.* 2014;35:899-905.

**Key Words:** quality of care, composite quality measure, quality metrics, Norwood operation, textbook outcome



**FIGURE E1.** Bar chart of N = 138 patients who did not achieve the textbook outcome, displayed as the number of patients versus number of postoperative complications experienced that compose the textbook outcome.

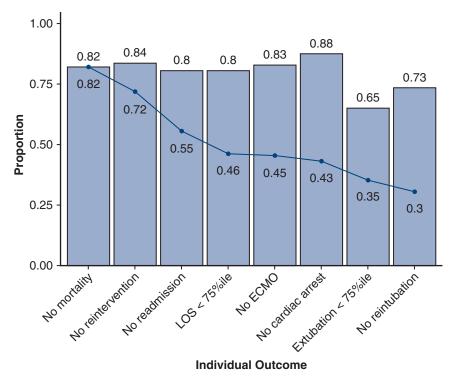


FIGURE E2. Patient proportion with HLHS that met individual postoperative outcomes that compose the textbook outcome (*above bar*) and proportion that cumulatively met each successive outcome (*below line*). LOS, Length of stay; ECMO, extracorporeal membrane oxygenation.

TABLE E1. Covariates included in multivariable Cox regression models to determine the independent effect of Norwood textbook outcome on overall postoperative survival

Covariates			
Age			
Weight			
Genetic syndrome or chromosomal abnormality			
Right ventricular dominance			
Prematurity			
Preoperative mechanical ventilation			
Preoperative shock			
Blalock-Taussig shunt			
Moderate-severe atrioventricular valve regurgitation			
Restrictive atrial septum (mean gradient >10 mm Hg)			
Moderate-severe systemic ventricular dysfunction			

 TABLE E2. Baseline patient characteristics and operative details for patients with HLHS

Characteristic	Achieved textbook outcome $(n = 39)$	Failed textbook outcome (n = 89)	P value
Demographics			
Male, N (%)	21 (54%)	56 (63%)	.30
Age, d, at surgery	4 (3-6)	5 (4-7)	.08
Prematurity,* N (%)	2 (5%)	12 (13%)	.20
Weight, kg	3.3 (3.0-3.7)	3.1 (2.7-3.5)	.02
Genetic syndrome or chromosomal abnormality, N (%)	3 (8%)	17 (19%)	.10
Diagnosis and imaging			
Anatomical diagnosis, N (%)			
HLHS	39 (100%)	89 (100%)	
Moderate-severe systemic AV valve regurgitation, N (%)	1 (3%)	11 (12%)	.10
Moderate-severe ventricular dysfunction, N (%)	2 (5%)	1 (1%)	.20
Restrictive interatrial septum, N (%)	8 (21%)	22 (25%)	.60
Obstructed anomalous pulmonary venous return, N (%)	0 (0%)	2 (2%)	>.90
Preoperative status			
Preoperative shock, N (%)	2 (5%)	22 (25%)	.009
Preoperative ventilator, N (%)	9 (23%)	36 (40%)	.06
Preoperative NEC, N (%)	1 (3%)	3 (3%)	>.9
Preoperative stroke or seizure, N (%)	2 (5%)	3 (3%)	.60
Operative details			
Cardiopulmonary bypass time, mins	161 (148-184)	183 (162-231)	.005
Blalock-Taussig shunt, N (%)	5 (13%)	12 (13%)	>.9

*HLHS*, Hypoplastic left heart syndrome; *AV*, atrioventricular; *NEC*, necrotizing enterocolitis. Bold values indicate P < .05. \*Gestational age < 37 wk. †Restrictive interatrial septum was defined as a mean gradient >10 mm Hg.

	Univariate analysis		Multivariable analysis	
N = 128 HLHS patients	OR (95% CI)	P value	OR (95% CI)	P value
Age, d	1.01 (0.96-1.06)	.70		
Weight, kg	2.40 (1.18-5.20)	.02	3.44 (1.45-9.00)	.007
Gender male	0.69 (0.32-1.48)	.30		
Syndromic or chromosomal abnormality	0.35 (0.08-1.14)	.11	0.32 (0.06-1.35)	.15
Prematurity	0.35 (0.05-1.36)	.20		
Preoperative neurologic deficit	1.55 (0.20-9.72)	.60		
Preoperative necrotizing enterocolitis	0.75 (0.04-6.11)	.80		
Preoperative ventilator	0.44 (0.18-1.01)	.06	0.47 (0.17-1.22)	.13
Preoperative shock	0.16 (0.03-0.60)	.02	0.11 (0.02-0.48)	.009
Moderate-severe systemic AV regurgitation	0.19 (0.01-1.01)	.11		
Moderate-severe ventricular dysfunction	4.76 (0.44-104)	.20		
Restrictive interatrial septum	0.79 (0.30-1.91)	.60		
CPB time (per min)	0.99 (0.98-1.00)	.007	0.98 (0.97-0.99)	.001
BT shunt	0.94 (0.28-2.76)	>.90		

## TABLE E3. Univariable and multivariable logistic regression to predict textbook outcome achievement in patients with HLHS

*HLHS*, Hypoplastic left heart syndrome; *OR*, odds ratio; *CI*, confidence interval; *AV*, Atrioventricular; *CPB*, cardiopulmonary bypass; *BT*, Blalock–Taussig. Bold values indicate *P* < .05.