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Technical performance score is associated with outcomes after the Norwood procedure

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Objectives: The technical performance score (TPS) has been reported in a single center study to predict the outcomes after congenital cardiac surgery. We sought to determine the association of the TPS with outcomes in patients undergoing the Norwood procedure in the Single Ventricle Reconstruction trial.

Methods: We calculated the TPS (class 1, optimal; class 2, adequate; class 3, inadequate) according to the predischarge echocardiograms analyzed in a core laboratory and unplanned reinterventions that occurred before discharge from the Norwood hospitalization. Multivariable regression examined the association of the TPS with interval to first extubation, Norwood length of stay, death or transplantation, unplanned postdischarge reinterventions, and neurodevelopment at 14 months old.

Results: Of 549 patients undergoing a Norwood procedure, 356 (65%) had an echocardiogram adequate to assess atrial septal restriction or arch obstruction or an unplanned reintervention, enabling calculation of the TPS. On multivariable regression, adjusting for preoperative variables, a better TPS was an independent predictor of a shorter interval to first extubation ($P = .019$), better transplant-free survival before Norwood discharge ($P < .001$; odds ratio, 9.1 for inadequate vs optimal), shorter hospital length of stay ($P < .001$), fewer unplanned reinterventions between Norwood discharge and stage II ($P = .004$), and a higher Bayley II psychomotor development index at 14 months ($P = .031$). The TPS was not associated with transplant-free survival after Norwood discharge, unplanned reinterventions after stage II, or the Bayley II mental development index at 14 months.

Conclusions: TPS is an independent predictor of important outcomes after Norwood and could serve as a tool for quality improvement. (J Thorac Cardiovasc Surg 2014;148:2208-14)

See related commentary on pages 2214-5.

Supplemental material is available online.

The technical performance score (TPS) is a quality improvement tool that was developed to determine the technical adequacy of an intended surgical procedure. It has been validated for a subset of common congenital cardiac operations at a single center.[1-8] For neonates undergoing the Norwood procedure at a single institution,

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The investigators and centers in the Single Ventricle Reconstruction Trial are listed in Appendix E1.

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Abbreviations and Acronyms

ASD = atrial septal defect
IQR = interquartile range
LOS = length of stay
MDI = mental developmental index
PA = pulmonary artery
PDI = psychomotor developmental index
SVR = single ventricle reconstruction
TPS = technical performance score

an optimal TPS mitigated the effects of the preoperative physiologic status and illness severity during the initial hospital stay.[2,3,9] However, the TPS requires validation in a multicenter study.

We sought to determine the validity of TPS across multiple centers using the database from the Pediatric Heart Network's Single Ventricle Reconstruction (SVR) trial.[10-15] Specifically, we explored whether the TPS could predict early and late outcomes, including resource usage. We hypothesized that the TPS could also identify patients at higher risk of reintervention in the interstage phase.

METHODS

We performed a secondary analysis of the data from the SVR trial, for which the inclusion and exclusion criteria, study design, and data collection have been previously described.[10-15]

Technical Performance Scoring System

All subjects were assigned a TPS according to the following data obtained before Norwood hospital discharge: postoperative, protocol-driven transthoracic echocardiographic findings interpreted by a core laboratory and unanticipated surgical or catheter-based reintervention in the areas of Norwood repair before discharge from the hospitalization associated with the Norwood procedure. The TPS module used in our analyses, as modified from the original reported by Bacha and colleagues,[2] is summarized in Table E1.

In brief, the surgical procedures were divided into components that were assigned a score of class 1 (optimal), class 2 (adequate), or class 3 (inadequate) according to specific echocardiographic criteria and the occurrence of unplanned reinterventions at surgical repair sites before discharge from the Norwood hospitalization (Table E1). The overall classification of the operation as class 1, 2 or 3 was determined from the highest class assignment for any of the component subprocedures. All components of the Norwood TPS module in its current version were given equal weight.

Two additional classes were created to allow the inclusion of all subjects in the SVR trial. Class 4 included subjects who had had no core laboratory echocardiograms and no unanticipated reinterventions in the area of Norwood repair before discharge or death. Class 5 included subjects with echocardiograms inadequate for TPS assignment and no unanticipated Norwood surgical reinterventions before discharge or death.

Outcomes

Our primary outcome was the interval to the initial endotracheal extubation, because it is a well known surrogate for resource usage. We did not choose mortality as our primary endpoint because a vast majority of class 4 (no echocardiogram) patients died and thus could not be assigned a TPS. The secondary outcomes included early mortality or transplantation, defined as occurring before Norwood discharge or within 30 days of the Norwood procedure if discharged before 30 days, whichever was longer; Norwood hospitalization length of stay (LOS); late mortality or transplantation; unplanned reinterventions after Norwood discharge; and the psychomotor development index (PDI) and mental development index (MDI) scores of the "Bayley Scales of Infant Development, 2nd edition."

Classification of Unplanned Reinterventions After Norwood Discharge

The following postdischarge reinterventions were considered to be attributable to the Norwood procedure technique: (1) any reintervention on the aortic arch, atrial septum, or ascending aorta or proximal pulmonary artery (PA) connection; (2) extensive PA rehabilitation, excluding simple PA augmentation at the stage II or Fontan procedure; and (3) any reintervention on the modified Blalock-Taussig shunt or right ventricle-to-PA shunt between Norwood discharge and the stage II procedure.

The following postdischarge reinterventions were considered not to be attributable to the Norwood procedure technique: (1) coiling of the aortopulmonary or venovenous collaterals; (2) an uncomplicated stage II procedure or Fontan procedure; and (3) any intervention on the superior vena cava after the stage II procedure or Fontan connections after the Fontan procedure.

Statistical Analysis

The distributions of patient and procedural characteristics by TPS class were compared using the chi-square or Fisher exact test for categorical variables and the Kruskal-Wallis test or 1-way analysis of variance for continuous variables.

Cox regression modeling identified the factors associated with the interval to the initial extubation. The factors associated on univariate analysis at the 0.20 level were candidate predictors for stepwise multivariable modeling. Our multivariable analyses included only the patient factors and preoperative medical variables, because the intraoperative and postoperative outcomes were in the causal pathway of the measures used to calculate the TPS. The TPS was then added to the multivariable model to assess whether it was an independent predictor. Kaplan-Meier estimation with the log-rank test described the association of the interval to initial extubation and the TPS. The same approach was applied to the secondary outcome variables, using linear regression for continuous variables and logistic regression for dichotomous outcomes. We assessed the reliability of the TPS as an independent predictor of each outcome by creating 1000 samples with bootstrapping to determine the percentage of samples in which the TPS was significant at the 0.05 level, conditional on the demographic and preoperative variables already in the multivariable model. A reliability of $\geq$50% was set as the criterion for retaining the TPS term as an independent predictor.

We assessed whether the 3 components of the TPS (distal arch gradient, atrial septal defect [ASD] gradient, and unplanned reinterventions before Norwood discharge) were associated with Norwood hospitalization LOS, early mortality or transplantation, and reintervention before the stage II procedure. For the echocardiographic components, the medium and high categories for the distal arch gradient and the mean ASD gradient were combined before modeling owing to sparse data.

Sensitivity analyses were also conducted, using the data from subjects with missing and incomplete echocardiograms (class 4 and 5, respectively). The TPS was assumed to be optimal for all, and then inadequate for all, to set the bounds on the relationships between the interval to initial extubation and technical performance.

All analyses were performed using Statistical Analysis Systems, version 9.3 (SAS Institute, Cary, NC).

RESULTS

The SVR trial randomized 555 subjects, of whom 5 did not undergo a Norwood procedure and 1 withdrew in the

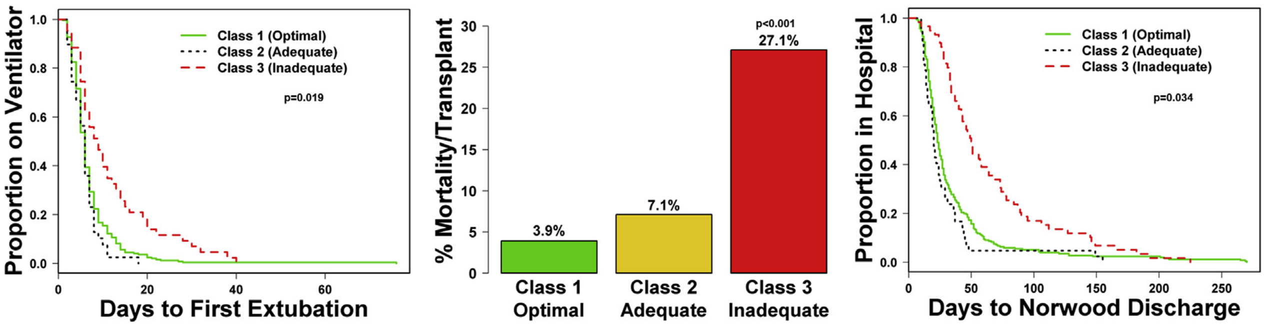

FIGURE 1. Interval to first extubation, early mortality, and Norwood hospital length of stay stratified by technical performance score class. Class 3 subjects had a significantly longer interval to first extubation, greater early mortality, and longer Norwood hospital length of stay.

first week. Of the remaining 549 subjects, 485 (88%) had postoperative echocardiograms adequate for calculating the TPS, and 452 (82%) survived transplant-free to Norwood discharge. Protocol-driven echocardiograms were performed at a median of 14 days (interquartile range [IQR], 8-21) postoperatively. A TPS could be assigned to 356 subjects (65%) using the echocardiograms or because of unanticipated reinterventions in the areas of Norwood repair. An additional 56 subjects (10%) were class 4 and 137 (25%) class 5. The baseline characteristics are listed in Table E2. The subjects in class 4 (no echocardiogram) had the lowest birth weight and the highest prevalence of preterm birth and percentage of unknown genetic status. No difference was found in the patient factors between those in class 5 and those with an assigned TPS (Table E3). Among the subjects with a TPS, the distribution was class 1 for 72%, class 2 for 12%, and class 3 for 17%.

Interval to First Extubation

Of the 452 subjects (82%) discharged after the Norwood procedure alive without transplantation, those with TPS class 3 underwent extubation later than those in class 1 or 2 (log-rank test, $P < .001$; Figure 1), with a median interval to extubation of 9 days (IQR 5-15), 6 days (IQR, 4-8), and 6 days (IQR, 3-7), respectively. After adjusting for center, the variables independently associated with a longer interval to first extubation included lower gestational age, Hispanic ethnicity, and the presence of a genetic syndrome or anomalies (model $R^2 = 0.21$). When added to this model, TPS was an independent predictor (model $R^2 = 0.23$, $P = .019$, 76% reliability). Class 3 subjects had a longer interval to first extubation (Table 1).

Early Mortality or Transplantation

Three pre-Norwood characteristics were independently associated with early mortality or transplantation: obstructed pulmonary venous return, cardiac or other surgery before the Norwood operation, and genetic syndrome or anomalies. When added to this model, TPS was an independent risk factor ($P < .001$, 98% reliability). Class 3 subjects had greater odds of early mortality or transplantation, and class 1 and 2 subjects had similar risks of early mortality or transplantation (Table E4 and Figure 1). The R^2 increased from 0.14 to 0.26 (Table 2).

Norwood Hospital LOS in Transplant-Free Survivors

The median LOS (n = 329) was significantly longer in those in class 3 than in those in class 1 and 2 (median 50 vs 23 and 20 days, respectively; Figure 1). The TPS was an independent predictor of the Norwood LOS ($P < .001$, 100% reliability) when added to the multivariable model that included center and genetic syndrome or anomalies. The R^2 increased from 0.15 to 0.20 (Table 3).

Late Reinterventions Attributable to the Norwood

The data were analyzed in 2 periods: after Norwood discharge but before stage II and after the stage II procedure. Of the 329 subjects with a TPS class, including 37 (11%) who died between Norwood discharge and stage II surgery, those in class 1 were the least likely to have required reintervention between Norwood discharge and stage II (logistic regression, $P = .003$; 78% reliability; Table 4 and Table E5). The TPS was not associated with late reinterventions from the stage II operation to age 12 months.

Mortality or Transplantation After Norwood Discharge

Of the 448 transplant-free survivors to Norwood discharge, 96 had died (n = 85) or underwent transplantation (n = 11) by 3 years after randomization. The independent predictors of a greater hazard of death or transplantation between Norwood discharge and 3 years after randomization included preterm delivery, obstructed pulmonary venous return, and greatest pre-Norwood lactate level. When added to this model, the TPS was not an independent predictor (Tables E6 and E7).

Neurodevelopmental Outcomes

The distributions of the PDI and MDI scores are presented in Figure E1. The independent preoperative

TABLE 1. Multivariable Cox regression model for interval to first extubation* (n = 324, R^2 = 0.23)

Variable	HR	95% CI	*P* value
Center			<.001
Gestational age (mo)	0.88	0.82-0.95	<.001
Hispanic			.03
Yes	1.40	1.04-1.90	
No	Reference		
Genetic syndrome or other anomalies			.03
Yes	1.51	1.12-2.06	
No	Reference		
Unknown	1.19	0.84-1.66	
TPS			.02
Class 1 (optimal)	0.59	0.41-0.85	
Class 2 (adequate)	0.62	0.38-1.00	
Class 3 (inadequate)	Reference		

All *P* values were statistically significant. *HR*, Hazard ratio; *CI*, confidence interval; *TPS*, technical performance score. *Excluding data from subjects who had died or underwent cardiac transplantation during hospitalization.

TABLE 3. Multivariable Cox regression model for Norwood length of stay* (n = 329, R^2 = 0.20)

Variable	HR (95% CI)	*P* value
Center		.01
Genetic syndrome or other anomalies		.001
Yes	1.63 (1.21-2.19)	
No	Reference	
Unknown	1.65 (1.18-2.30)	
TPS		<.001
Class 1 (optimal)	0.44 (0.31, 0.63)	
Class 2 (adequate)	0.35 (0.22, 0.56)	
Class 3 (inadequate)	Reference	
Pre-Norwood complication		.03
Yes	1.33 (1.02-1.72)	
No	Reference	

All *P* values were statistically significant. *HR*, Hazard ratio; *CI*, confidence intervals; *TPS*, technical performance score. *Excluding data of subjects who died or underwent cardiac transplant during the hospitalization.

predictors of a lower PDI score were center, lower birth weight, and genetic syndrome or anomalies. When the TPS was added to the model, a worse TPS class was associated with a lower PDI score (P = .031, 66% reliability), with the model R^2 increasing from 0.19 to 0.22. A lower MDI score was independently associated with center, lower birth weight, lower Apgar score at 1 minute, intubation for respiratory failure or metabolic acidosis, and genetic syndrome or anomalies. When added to this model, the TPS class was not associated with the MDI score.

TPS Components

We analyzed the 3 components of the TPS available in the SVR trial database (distal arch gradient, ASD gradient, and unplanned predischarge reintervention in the areas of Norwood repair) to test their associations with the selected outcomes. Unplanned predischarge reinterventions in the areas of Norwood repair could occur in any component of the Norwood TPS. The reinterventions that resulted in class 3 TPS assignment are listed in Table E8, and the echocardiographic findings in the 59 subjects assigned to class 3 are summarized in Table E9. In multivariable analysis, pre-Norwood discharge reintervention was significantly associated with a greater early mortality or transplantation rate (odds ratio, 8.36; 95% confidence interval, 3.54-19.7; P < .001) and longer median Norwood LOS (51 days, IQR, 33-86; vs 23 days, IQR, 16-36; P < .01). A distal arch gradient of ≥20 mm Hg was significantly associated with a greater odds of prestage II reintervention (odds ratio, 3.28, 95% confidence interval, 1.59-6.76; P < .001). The ASD gradient was not associated with these 3 outcomes.

Sensitivity Analyses

To assess the effect of the exclusion of class 5 (incomplete echocardiograms) on the interval to first extubation, we included 137 class 5 subjects in the Cox regression analyses under 2 extreme assumptions: that all were class 1 and that all were class 3. When all class 5 subjects were assumed be class 1, the TPS remained a

TABLE 2. Multivariable logistic regression model for early death or transplantation (n = 356, R^2 = 0.26)

Variable	OR	95% CI	*P* value
Pre-Norwood intubation	2.38	1.01-5.61	.05
Genetic syndrome or other anomalies			.002
Yes	0.83	0.23-3.01	
No	Reference		
Unknown	4.43	1.72-11.4	
TPS			<.001
Class 1 (optimal)	0.11	0.04-0.26	
Class 2 (adequate)	0.19	0.05-0.75	
Class 3 (inadequate)	Reference		

All *P* values were statistically significant. *OR*, Odds ratio; *CI*, confidence interval; *TPS*, technical performance score.

TABLE 4. Multivariable logistic regression model for prestage II reintervention (n = 318, R^2 = 0.12)

Variable	OR	95% CI	*P* value
Prenatal diagnosis of CHD			.01
Yes	2.77	1.24-6.18	
No	Reference		
SES score	1.06	1.01-1.12	.03
TPS			.01
Class 1 (optimal)	Reference		
Class 2 (adequate)*	2.93	1.41-6.11	
Class 3 (inadequate)	2.02	0.94-4.32	

All *P* values were statistically significant. *OR*, Odds ratio; *CI*, confidence interval; *CHD*, congenital heart disease; *SES*, socioeconomic status; *TPS*, technical performance score. *Class 2 versus 3 did not differ (P = .681).

CHD

significant ($P < .001$) independent predictor. In contrast, when all class 5 subjects were presumed to be class 3, the TPS was no longer associated ($P = .99$) with the interval to first extubation. However, because the characteristics of the subjects with an incomplete echocardiogram were similar to those with an assignable TPS, this latter sensitivity assumption (100% class 3) was discordant with the observed percentage of subjects with a score who were assigned to class 3 (17%).

We did not perform a sensitivity analysis regarding the interval to first extubation for class 4 (no echocardiogram), because only 2 of the 56 class 4 subjects survived to Norwood discharge and had interval-to-extubation data. Instead, we performed a sensitivity analysis using the regression model for early mortality or transplantation and included the class 4 subjects, assuming that all had either class 1 or 3 TPS. When class 4 subjects were all assumed to be class 1, the TPS remained associated ($P = .050$) with early mortality or transplantation. However, we would expect that class 4 subjects would be most likely to have had an inadequate TPS (class 3) rather than an optimal TPS (class 1), because 96% of the class 4 subjects died or underwent transplantation. When the class 4 subjects were all assigned to class 3, the TPS was strongly associated with mortality ($P < .001$).

DISCUSSION

Although the role of human factors in the outcomes after surgery has been well described,[16-18] the technical adequacy of the repair could still be the single most important factor in determining the outcomes. This premise has been proved in other surgical fields[19-21] in which assessment models have been based on methods such as video recordings, and models of surgical skills assessment have been incorporated into surgical training programs.[22-25] However, a tool using routine clinical information for measurement of technical adequacy has not been validated. As previously described at a single center,[3-9] the TPS is based on information available from routine clinical care, including postoperative echocardiographic findings and reintervention in the anatomic areas of surgical repair. Moreover, the TPS has been associated with early outcomes, such as mortality, major adverse events, longer LOS, and higher costs, and mid-term outcomes after hospital discharge, such as transplant-free survival and unplanned reinterventions.

In the present multicenter study, we found that the TPS was an independent predictor of both early and mid-term outcomes after the Norwood procedure. Specifically, our multivariable model, which included baseline patient factors and preoperative variables, found that a worse TPS was significantly associated with a longer interval to first extubation, greater early mortality or transplantation, a longer Norwood LOS, more unanticipated interventions between Norwood discharge and the stage II procedure, and lower PDI scores at 14 months of age. We did not find an association between the TPS and unanticipated reinterventions after the stage II procedure, the 14-month MDI score, or late mortality or transplantation. The association of a worse TPS with a lower 14-month PDI score but not MDI score is consistent with the nearly universal observation that the PDI scores are more affected than the MDI scores in children with congenital heart disease.[26-29] Early death in subjects with inadequate repair might explain the lack of an association of the TPS with late mortality or transplantation and the greater rate of reintervention before stage II among the subjects in class 2 compared with class 3. Analyses of the components of the TPS showed that reinterventions were significantly associated with early mortality and Norwood LOS, and higher arch gradients were associated with prestage II reinterventions. The present multicenter study has validated the generalizability of the TPS across centers that vary widely in geographic location and volume.

The effect of the TPS on Norwood outcomes is relatively modest compared with that of the other independent risk factors measured in the SVR trial. This was, in part, because the regression models in the present study could not include the intraoperative and postoperative variables that are in the causal pathway of the factors on which calculation of the TPS is based. For example, in an earlier report from the SVR trial,[30] extracorporeal membrane oxygenation and an open sternum on the day of the Norwood procedure were among the most powerful independent predictors of 30-day and hospital mortality and the interval to first extubation after the Norwood procedure, the primary outcome in our study. Similarly, the independent predictors of interstage mortality included the use of a modified Blalock-Taussig shunt rather than a right ventricular-to-PA shunt in subjects with no or mild postoperative atrioventricular valve regurgitation and greater number of post-Norwood complications.[31] Our regression models did, however, consider patient and preoperative medical risk factors previously shown to be independent risk factors of adverse outcomes before Norwood discharge and in the interstage, such as low birthweight,[30] lower gestational age,[31] and anatomic factors[31] (eg, the presence of aortic atresia or mitral atresia). The TPS is among the most modifiable of the various risk factors demonstrated in the SVR trial.

The TPS has been based on the transthoracic echocardiogram performed before hospital discharge. A scoring system for intraoperative echocardiography might provide timely information and elucidate components of an "inadequate" procedure that would benefit from immediate intraoperative revision. Recent work has shown that intraoperative revision of residual lesions improves in-hospital outcomes.[5]

Our analysis should be viewed in light of its limitations. We were unable to calculate the TPS for one third of the subjects because of missing or incomplete protocol echocardiograms, together with the absence of reinterventions at the sites of initial surgical correction. Mortality was a secondary study outcome, because its analysis with respect to TPS was conditional on early survival (ie, the vast majority of subjects without echocardiograms [91%] died early—before the protocol echocardiogram was performed [class 4 subjects]). Although it seems likely that most of these subjects would have had a class 3 TPS, our study design did not allow us to test this hypothesis directly. In the sensitivity analyses, assuming that all these subjects had either class 1 or 3 TPS, the TPS remained an independent predictor of mortality before Norwood discharge. The primary endpoint of the present study, the interval to initial extubation, might have been affected by center practices and protocols. However, the center was considered as a covariate in the multivariable models, and other measures of overall hospital complexity, such as the LOS in the cardiac intensive care unit, would have been even more affected by center variation.[32] Finally, the components of the TPS were derived by the consensus of experts, rather than by determination of cutpoints from analyses of prospectively collected data, and TPS classes 1 and 2 were often similar in their prediction of the outcomes. A prospective multicenter study of the Pediatric Heart Network, currently in its planning phase, will refine the cutpoints of the TPS using both a multicenter expert panel and an analysis of prospectively collected data.

CONCLUSIONS

The TPS is an independent predictor of both early and mid-term outcomes in patients with hypoplastic left heart syndrome and other single right ventricle anomalies undergoing the Norwood procedure. With additional multicenter refinement and testing, the TPS could be used as a tool for quality improvement, with the potential for impact, not only on patient outcomes, but also on resource usage in this costly, high-risk population.

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EDITORIAL COMMENTARY

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Utility of the technical performance score for the Norwood operation … every score should know its limitations

Tara Karamlou, MD

See related article on pages 2208-14.

The article by Nathan and colleagues[1] in this issue of the *Journal* provides additional data regarding the relationship of the technical performance score (TPS) to outcomes after the Norwood procedure among participants of the Single Ventricle Reconstruction Trial (SVR). Nathan and colleagues[1] conducted an ad hoc analysis of the SVR cohort of neonates undergoing the Norwood operation. By means of discharge echocardiography, available for 365 (65%) of the 549 patients in the study, a TPS category of optimal (72%), adequate (12%), or inadequate (17%), was assigned. The components of the TPS, which are weighted equally, include restriction at the atrial septum, residual aortic arch obstruction, and intervention on the chosen source of pulmonary blood flow. Neurodevelopmental outcome was assessed with the Bayley Scales of Infant Development (2nd edition). By means of multivariable regression, Nathan and colleagues[1] found that better TPS was associated with shorter time to initial extubation, improved transplant-free survival before discharge after the Norwood operation, shorter hospital stay, lower prevalence of unplanned interstage interventions, and better Bayley Scales Psychomotor Developmental Index (PDI) subscale scores at 14 months.

I applaud Nathan and colleagues[1] for extending their considerable work in this area and for using a multi-institutional cohort with prospectively collected data. The TPS has promise as the first objective tool that can both inform care and provide a platform for individual surgeon evaluation. There are important limitations to this study, however, that should temper Nathan and colleagues' conclusions[1] regarding the impact of the TPS on post-Norwood outcomes.

Factors that affect outcomes after the Norwood operation have been studied in detail with both prospective and retrospective data. It is clear from the majority of these studies that surgeon, institution, and patient factors play critical roles; however, the relative contributions of each component remain unknown and vary with different lesions and procedures. In analysis of arguably the best data collection available,[2-4] surgeon factors in the Norwood operation, including volume and experience (ostensibly a surrogate for technical performance), were identified as having minor influence on mortality relative to center or patient

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APPENDIX E1. SINGLE VENTRICLE RECONSTRUCTION TRIAL PARTICIPANTS

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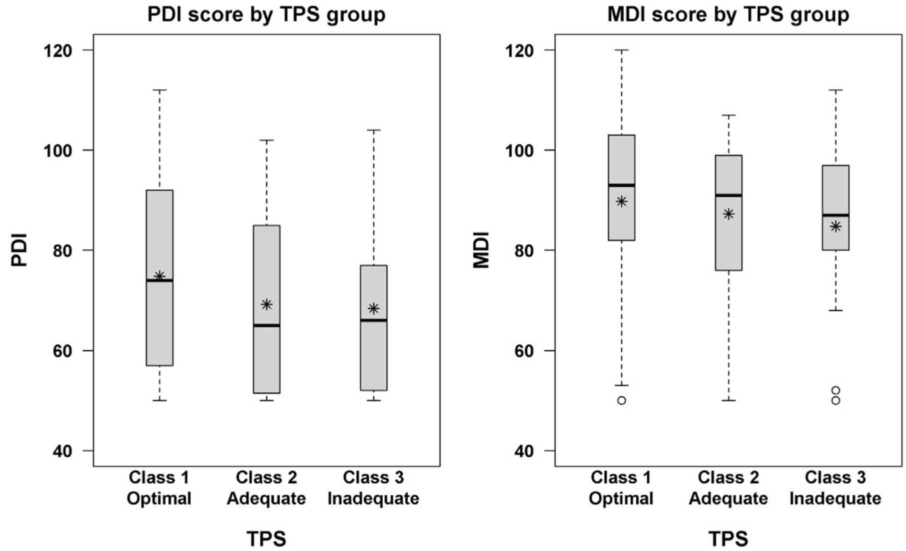

FIGURE E1. Box plots of Bayley psychomotor developmental index (*PDI*) and mental developmental index (*MDI*) scores by technical performance score (*TPS*) class. Those with class 1, optimal TPS, had higher MDI and PDI scores. Asterisk represents the mean, and the bottom, center, and top edges of the box represent the 25th, 50th, and 75th percentiles.

TABLE E1. Modified technical performance score module for Norwood procedure used to assign TPS in the SVR cohort

Subprocedure	Class 1 (optimal)	Class 2 (adequate)	Class 3 (inadequate)
Proximal arch reconstruction	NA	NA	Reintervention
Distal arch reconstruction	Peak gradient < 20 mm Hg	Peak gradient 20-40 mm Hg	Reintervention or peak gradient > 40 mm Hg
Coronary perfusion	NA	NA	Reintervention
Atrial septectomy	Mean gradient < 2 mm Hg	Mean gradient 3-4 mm Hg	Reintervention or mean gradient > 4 mm Hg
MBTS	Patent	Patent	Reintervention
RV-PA conduit	Patent	Patent	Reintervention

The final score is class 1 (optimal) if all subprocedure scores are optimal. The final score is class 2 (adequate) if any subprocedure score is adequate, but no subprocedure score is inadequate. The final score is class 3 (inadequate) if any subprocedure score is inadequate. *NA*, Not assessed in SVR trial core laboratory; *MBTS*, modified Blalock-Taussig shunt; *RV-PA*, right ventricle-to-pulmonary artery.

TABLE E2. Patient and Norwood procedural characteristics

Characteristic	Total (n)	Value	Median (IQR)
Demographic data			
Male sex	549	340 (62)	
Birth weight (kg)	549	3.1 ± 0.5	3.1 (2.8-3.5)
Birth weight < 2.5 kg	549	76 (14)	
Gestational age (wk)	549	38.2 ± 1.6	38 (37-39)
Gestational age < 37 wk	549	64 (12)	
Hispanic	539	101 (19)	
Race	544		
White		436 (80)	
Black		86 (16)	
Other		22 (4)	
1-min Apgar (after imputation)	549	7.6 ± 1.6	8 (8-9)
5-min Apgar (after imputation)	549	8.6 ± 0.8	9 (8-9)
Before Norwood			
Prenatal diagnosis of CHD	549	420 (77)	
Fetal intervention	549	14 (3)	
HLHS	549	474 (86)	
Aortic atresia	549	343 (63)	
Obstructed pulmonary venous return	549	19 (4)	
Highest lactate level (mmol/L; after imputation)	549	3.9 ± 2.9	3.0 (2.5-4.0)
Ever intubated	547	263 (48)	
For apnea	547	75 (14)	
For shock	547	14 (3)	
For respiratory failure	547	72 (13)	
For metabolic acidosis	547	31 (6)	
Cardiac and other surgery	549		
Yes		11 (2)	
No		538 (98)	
Cardiac catheterization intervention	549		
Yes		28 (5)	
No		521 (95)	
Complications	549		
Yes		153 (28)	
No		396 (72)	
No. of complications		0.6 ± 1.2	0 (0-1)
Age at Norwood procedure (d)	549	5.8 ± 4.1	5 (3-7)
Weight at Norwood procedure (kg)	549	3.1 ± 0.5	3.2 (2.8-3.5)
Norwood hospitalization*			
Crossclamp time (min)	549	56.0 ± 23.4	53 (40-67)
Total support time (min)	549	143.9 ± 54.1	139 (105-171)
Perfusion type	544		
DHCA		296 (54)	
RCP		130 (24)	
DHCA and RCP		118 (22)	
DHCA duration (min)	544	31.7 ± 23.2	0 (0-51)
RCP duration (min)	546	23.8 ± 29.2	0 (0-117)
Exterior diameter of AA at STJ (mm)	535	3.12 ± 1.66	2.5 (2.0-4.0)
ICU total LOS (d)	539	25.8 ± 33.8	14.0 (9.0-28.0)
Open sternum postoperatively	544	426 (78)	
Pacemaker insertion at or after operation	544	6 (1)	
Oxygen saturation at discharge (%)	436	82.4 ± 4.9	82 (80-85)

Data presented as n, n (%), or mean ± standard deviation, unless otherwise noted. *IQR*, Interquartile range; *CHD*, congenital heart disease; *HLHS*, hypoplastic left heart syndrome; *DHCA*, deep hypothermic circulatory arrest; *RCP*, regional cerebral perfusion; *AA*, ascending aorta; *STJ*, sinotubular junction; *ICU*, intensive care unit; *LOS*, length of stay. *These postbaseline factors were not used as candidate predictors in the modeling of outcomes.

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TABLE E3. Baseline characteristics of patients with and without TPSs

Characteristic	TPS assignable (class 1, 2, 3)	Class 4*	Class 5†	*P* value
Patients (n)	356	56	137	
Center				<.001‡
Demographic data				
Male sex	216 (61)	29 (52)	95 (69)	.05
Birth weight (kg)	3.1 ± 0.5	2.9 ± 0.6	3.2 ± 0.5	.02‡
Birth weight < 2.5 kg	44 (12)	17 (30)	15 (11)	<.001‡
Gestational age (wk)	38.2 ± 1.6	37.6 ± 1.9	38.3 ± 1.5	.03‡
Gestational age < 37 wk	37 (10)	13 (23)	14 (10)	.02‡
Hispanic	74 (21)	5 (9)	22 (16)	.09
Race				.73
White	287 (82)	43 (77)	106 (78)	
Black	50 (14)	11 (20)	25 (18)	
Other	15 (4)	2 (4)	5 (4)	
1-min Apgar (after imputation)	8.0 (8.0-9.0)	8.0 (8.0-8.0)	8.0 (8.0-8.0)	.23
5-min Apgar (after imputation)	9.0 (8.0-9.0)	9.0 (8.0-9.0)	9.0 (8.0-9.0)	.11
SES score	0.1 ± 5.1	−0.8 ± 5.9	−0.3 ± 4.6	.43
Below poverty level (%)	12.6 ± 12.6	14.2 ± 14.2	13.2 ± 12.0	.67
Pre-Norwood				
Prenatal diagnosis of CHD	274 (77)	43 (77)	103 (75)	.92
Fetal intervention	8 (2)	0 (0)	6 (4)	.18
HLHS	307 (86)	44 (79)	123 (90)	.12
Aortic atresia	217 (61)	35 (63)	91 (66)	.53
Obstructed pulmonary venous return	8 (2)	4 (7)	7 (5)	.08
Highest lactate level (mmol/L)	3.9 ± 2.9	3.7 ± 2.6	3.9 ± 3.0	.87
Ever intubated	162 (46)	32 (57)	69 (50)	.27
For apnea	41 (12)	9 (16)	25 (18)	.14
For shock	9 (3)	3 (5)	2 (2)	.30
For respiratory failure	48 (14)	7 (12)	17 (12)	.93
For metabolic acidosis	21 (6)	3 (5)	7 (5)	.93
Cardiac and other surgery	7 (2)	0 (0)	4 (3)	.42
Cardiac catheterization intervention	18 (5)	3 (5)	7 (5)	.99
Complications	98 (28)	19 (34)	36 (264)	.54
At Norwood operation				
Age (d)	5.8 ± 4.2	5.5 ± 3.5	5.9 ± 3.9	.82
Weight (kg)	3.1 ± 0.5	2.9 ± 0.6	3.1 ± 0.5	.004‡
Weight-for-age z score (WHO)	−0.6 ± 1.2	−1.2 ± 1.3	−0.6 ± 1.1	.010‡
Exterior diameter of AA (mm)	3.1 ± 1.6	3.0 ± 1.6	3.2 ± 1.8	.79
Genetic syndrome or other anomalies				<.001‡
Yes	78 (22)	6 (11)	35 (25)	
No	175 (49)	7 (13)	73 (53)	
Unknown	103 (29)	43 (77)	29 (21)	

Data presented as n (%), mean ± standard deviation, or median (interquartile range). *TPS*, Technical performance score; *SES*, socioeconomic status; *CHD*, congenital heart disease; *HLHS*, hypoplastic left heart syndrome; *WHO*, World Health Organization; *AA*, ascending aorta. *No TPS assigned because no echocardiogram performed and no unplanned reinterventions required before discharge. †No TPS assigned because of an incomplete echocardiogram and no unplanned reinterventions required before discharge. ‡Statistically significant.

TABLE E4. Early mortality or transplantation rate stratified by TPS class

Variable	Patients (n)	Transplantation or death (n)	Transplantation (n)	Death (n)
Overall	549	101 (21)	9	92
TPS				
Class 1 (optimal)	255	10 (4)	3	7
Class 2 (adequate)	42	3 (7)	0	3
Class 3 (inadequate)	59	16 (27)	2	14
Class 4 (no ECG, no RI)	56	54 (96)	3	51
Class 5 (incomplete ECG, no RI)	137	18 (13)	1	17

Data in parentheses are percentages. *TPS*, Technical performance score; *ECG*, echocardiogram; *RI*, reintervention.

TABLE E5. Prestage II reintervention stratified by TPS

Variable	Patients (n)	Reintervention	OR (95% CI)	*P* value
Overall	329	77 (23)		
TPS				.003*
Class 1 (optimal)	247	47 (19)	0.30 (0.15-0.62)	
Class 2 (adequate)	39	17 (44)	1.78 (0.72-4.42)	
Class 3 (inadequate)	43	13 (30)	Reference	

Data presented as n (%), unless otherwise noted. *TPS*, Technical performance score; *OR*, odds ratio; *CI*, confidence interval. *Statistically significant.

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TABLE E6. Late mortality or transplantation from Norwood discharge to 3 years after randomization

Variable	Patients (n)	Transplantation or death (n)	Transplantation (n)	Death (n)
Overall	448	96 (21)	11	85
TPS				
Class 1 (optimal)	245	55 (55/242 [23])*	6	49
Class 2 (adequate)	39	5 (5/38 [13])*	1	4
Class 3 (inadequate)	43	9 (9/42 [21])*	2	7
Class 4 (no ECG)	2	2 (100)	0	2
Class 5 (incomplete ECG)	119	25 (26)	2	23

Data in parentheses or brackets are percentages. The data of the subjects who died or underwent cardiac transplantation before Norwood discharge were excluded. *TPS*, Technical performance score; *ECG*, echocardiogram. *The denominators reflect the exclusion of the 5 patients who withdrew 13 to 16 months after randomization.

TABLE E7. Multivariable Cox regression model for late mortality or transplantation from Norwood discharge to 3 years after randomization (n = 327)

Variable	HR	95% CI	*P* value
Gestational age < 37 wk			.010*
Yes	2.32	1.23-4.41	
No	Reference		
Obstructed pulmonary venous return	5.43	1.66-17.8	.005*
Highest lactate level (mmol/L)	1.11	1.05-1.18	<.001*
TPS			.390
Class 1 (optimal)	1.37	0.67-2.82	
Class 2 (adequate)	0.80	0.26-2.45	
Class 3 (inadequate)	Reference		

The data of subjects who died or underwent cardiac transplant before Norwood discharge were excluded. *HR*, Hazard ratio; *CI*, confidence interval; *TPS*, technical performance score. *Statistically significant.

TABLE E8. Types of unplanned reinterventions in anatomic areas of surgical repair during Norwood hospitalization in class 3 patients stratified by shunt type

Unplanned reintervention	BTS (n)	RVPAS (n)
Shunt	20	24
Surgical thrombectomy	2	0
Catheter RI	6	10
Shunt crossover	5	7
Surgical revision	7	7
Arch	3	1
Branch PA	4	2
ASD	1	0
Total	28	27

For the entire cohort of 55 patients, 9 patients had no ECGs and 13 had incomplete ECGs. *BTS*, Blalock-Taussig shunt; *RVPAS*, right ventricle-to-pulmonary artery shunt; *RI*, reintervention; *PA*, pulmonary artery; *ASD*, atrial septal defect.

TABLE E9. Echocardiographic findings of 59 class 3 patients

Arch peak velocity (m/s)	ASD mean gradient (mm Hg)	RI	Patients (n)
<2.25*	<2	Proximal arch	1
2.25-3.2†	<2	Proximal arch	1
Missing	Missing	Proximal arch	1
2.25-3.2	>4	Atrial septectomy	1
<2.25	>4	Atrial septectomy and RI	1
Missing	Missing	Shunt RI	8
Missing	<2	Shunt RI	13
<2.25	<2	Shunt RI	27
2.25-3.2	Missing	Shunt RI	1
2.25-3.2	<2	Shunt RI	1
<2.25	>4	None	1
>3.2‡	<2	None	3

ASD, Atrial septal defect; *RI*, reintervention. *<2.25 m/s = <20 mm Hg. †2.25-3.2 m/s = 20-40 mm Hg. ‡>3.2 m/s = >40 mm Hg.

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