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Current Practices in the Timing of Stage-2-Palliation: A Survey of the CHSS and ECHSA

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Abstract

Background: Mortality through single ventricle palliation remains high and the effect of the timing of Stage-2-Palliation (S2P) is not well understood. We investigated current practice patterns in the timing of S2P across two professional societies and compared them to actual practice patterns from two databases of patients who underwent S2P.

Methods: A 10-question survey was distributed to the members of the Congenital Heart Surgeons' Society (CHSS) and the European Congenital Heart Surgeons' Association (ECHSA). Results were summarized using descriptive statistics. Surgeon-reported preferences were compared to clinical data from the CHSS Critical LVOTO Registry and the Pediatric Heart Network Single Ventricle Reconstruction database.

Results: Overall, 38% (88/232) of surgeons from 74 institutions responded, of which 70% (62/88) were CHSS members and 30% (26/88) were ECHSA members. Surgeons reported performing S2P at a median of 5 months after Stage 1 (IQR 4.5–6), with no difference between

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CHSS and ECHSA surgeons. Surgeons reported performing non-elective S2P at a median of 4.5 months after Stage 1 (IQR 3.5–5.5), again with no difference by society. No difference existed between surgeon-reported preferences and patient data in the Critical LVOTO and SVR databases for the timing of elective (5 vs. 5.1 vs 5.3 months, $p=0.19$) or non-elective S2P (4.5 vs. 4.6 vs. 4.2 months, $p=0.06$).

Conclusions: There was a remarkable lack of variation in surgeon preferences regarding the timing of S2P. This may represent a natural standardization of practice across congenital heart surgery, which is notable given the current lack of guidelines regarding the timing of S2P.

Keywords

Hypoplastic left heart syndrome; database; congenital heart surgery; cavopulmonary anastomosis

Introduction:

Mortality in patients who require three-stage single ventricle palliation remains high, especially after the Stage 1 operation. Estimates for mortality after Stage 1, especially during the first “interstage” period, defined as the day Stage 1 hospitalization discharge until the day of Stage-2-Palliation (S2P), range from 2–20% (1, 2). Survival after S2P is much higher, often greater than 90% (3–6). However, the long-term, actuarial survival through the three stages of single ventricle palliation does remain discouraging, with survival rates of approximately 65% (7, 8).

Along with programs such as home surveillance, nutritional supplementation, and hospital readmission, the timing of S2P represents a physician-modifiable factor that may affect survival during single ventricle palliation. But, its importance is not yet well understood and little evidence is available to guide decision making regarding the timing of surgery. Younger age at S2P has been identified as a risk factor in several uni- and multivariable analyses (9–11). On the other hand, several other studies have not implicated age at S2P or the interval from Norwood to S2P as a risk factor. A secondary analysis of the Pediatric Heart Network’s Single Ventricle Reconstruction (SVR) Trial did not find that age or interval length was a risk factor for morbidity or extended length of stay after S2P (12).

While patient data has been reported, surgeon preferences regarding the timing of S2P have not yet been evaluated in a multi-institutional study. Moreover, surgeon-reported preferences may differ from patient data. In this survey of the Congenital Heart Surgeons’ Society (CHSS) and European Congenital Heart Surgeons’ Association (ECHSA), we sought to understand surgeon preferences for the timing of S2P and compare this surgeon-reported data to two well-known clinical data sets of patients requiring three-stage single ventricle palliation.

Methods:

Study design

A survey of 10 questions was designed to gain insight into individual surgeon preferences in the timing of S2P (Figure 1). S2P was defined as a cavopulmonary connection and any

simultaneous procedures following a Stage 1 operation. “Non-elective” S2P was defined as progression to S2P outside of the surgeons’ typical timeframe for S2P, due to pathology or a clinical condition that was amenable to surgical intervention (versus delay due to a medical illness such as a respiratory infection). The survey was distributed to the surgeon members of the CHSS and ECHSA via an individualized email link and was available for five weeks. Study data was collected and managed using the REDCap electronic data capture tools hosted at the Hospital for Sick Children. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources (13). All surgeon participants provided implied informed consent. Ethical approval for the study was obtained from the Hospital for Sick Children Research Ethics Board.

Comparison data sets

Surgeon-reported data from the survey was compared to patient data from the CHSS Critical LVOTO Registry and the Pediatric Heart Network’s (PHN) SVR Trial public data set. Critical LVOTO was defined as left ventricular obstruction that precluded systemic perfusion through the aortic valve. Patients included in the comparison group were less than 30 days old at admission to a CHSS institution, and had concordant atrioventricular and ventriculo-arterial connections. For comparison, 377 infants who underwent an initial Norwood operation and then either a Bidirectional Glenn or Hemi-Fontan for S2P were included.

The SVR Trial’s design, inclusion criteria, methods, and results have been discussed in detail previously (14, 15). The NIH/NHLBI PHN SVR Trial dataset was used in preparation of this work and was downloaded from https://www.pediatricheartnetwork.com/pud_login.asp?study_id=SVR on August 6, 2015. For the comparison group, 399 of the 401 patients who underwent S2P in the SVR Trial were included. One patient was excluded due to lack of sufficient information about S2P. The other patient was a single extreme outlier who may have biased the analysis.

Statistical analysis

Descriptive statistics were computed. The normality of the distribution of all data was determined using the Shapiro-Wilkes test. Categorical variables were summarized using percentages and raw proportions and compared using Fisher’s exact test. Continuous variables were summarized using medians and Interquartile Ranges (IQR) and compared using the Mann-Whitney U or Kruskal-Wallis test. A p-value of less than 0.05 was considered significant. The intervals reported from Norwood to S2P were calculated as the average of the values earliest and latest preferences for S2P. All statistical analyses performed using SAS version 9.2 (SAS Institute, Inc., Cary, NC).

Results:

Response rate

The response rate was 38%, or 88/232 surgeons, from 74 total institutions. CHSS surgeons comprised 70% of respondents, from 49 institutions. ECHSA surgeons comprised 30% of respondents, from 25 institutions.

Preferences in the Timing of S2P

The median surgeon-reported interval from Stage 1 to S2P in patients who underwent “elective” or “planned” S2P was five months (IQR 4.5–6, Table 1). The minimum and maximum reported interval lengths were three and eight months, respectively. The median interval for surgeon members of each society did not differ ($p=0.97$, Table 1). Three-quarters of surgeons indicated that the type of stage 1 operation (Norwood operation with a right-ventricle-to-pulmonary artery conduit, Norwood operation with a Blalock-Taussig shunt, or Hybrid Stage 1) did not affect when they prefer to perform elective S2P. The remainder of surgeons were nearly evenly distributed between the type of stage 1 operation after which they prefer to perform S2P earliest. No differences existed between the two societies in the type of stage 1 operation after which they prefer to perform S2P earliest, as well ($p=0.50$, Table 2).

Surgeon-reported preferences for the timing of elective S2P did not differ significantly when compared to the median intervals for patients undergoing S2P in the CHSS Critical LVOTO cohort and SVR Trial, 5 vs. 5.1 vs. 5.3 months, respectively ($p=0.19$, Table 3). The minimum and maximum interval lengths in the CHSS Critical LVOTO registry were 1.6 and 17.2 months, respectively, and were 1.6 and 12.3 months in the SVR Trial, respectively. These comparisons are displayed graphically in Figure 2.

The median surgeon-reported interval from Stage 1 to S2P in patients who underwent “non-elective” or “unplanned” S2P for pathology thought to be amenable to surgical intervention was 4.5 months (IQR 3.5–5.5, Table 1). The minimum and maximum reported interval lengths were two and seven months, respectively. Each society’s median interval did not differ ($p=0.15$, Table 1). Surgeon-reported preferences for the timing of non-elective S2P nearly differed when compared to clinical data from the CHSS Critical LVOTO cohort and SVR Trial, 4.5 vs. 4.6 vs. 4.2 months, respectively ($p=0.06$, Table 3). The minimum and maximum interval lengths in the CHSS Critical LVOTO registry were 1.0 and 16.7 months, respectively, and were 1.5 and 9.9 months in the SVR Trial, respectively. Figure 3 shows the distributions of intervals in each data set.

Pre-S2P Protocols and Programs

Surgeons were queried regarding specific aspects of their pre-S2P care. First, 75% indicated that their institutions discharged patients with home monitoring programs. The utilization of these programs did differ by society, with 90% of CHSS respondents vs. 38% of ECHSA respondents indicating the presence of a home monitoring program ($p < 0.0001$, Table 4). One third surgeons with home monitoring programs had specific indications for early transition to S2P or hospital admission built in into their home monitoring programs. This

did not differ by society ($p=0.62$). Less than 20% of respondents from both societies indicated that specific indications for early S2P did not exist (Table 4). Only 27% indicated that their institutions had protocols in place for elective progression to S2P, which nearly differed by society ($p=0.05$). Amongst those with protocolized paths, S2P was most frequently performed at four or five months after Stage 1 (Table 4).

Comment:

In this survey study of congenital heart surgeons from North America and Europe, no significant differences existed between North American and European surgeons' preferences for the timing of S2P. No difference existed also between surgeon-reported preferences and patient data from two large cohorts of patients requiring single ventricle palliation, as well. The type of stage 1 operation did not affect surgeon decision making regarding timing of surgery. However, the distributions of home monitoring programs did differ.

The timing of S2P

We report that surgeons in the CHSS and ECHSA favor performing elective S2P at five months after the Stage 1 operation. As shown in Figure 2, there was little deviation from the central tendency, the median of five months after Stage 1, with a minimum of three months and a maximum of eight months after Stage 1 and an IQR of 4–6 months. Many studies of the outcomes after Stage 2 do not differentiate specifically between elective and non-elective status of S2P, making the contextualization of these results difficult. Some evaluate the effects of a deliberate strategy of early S2P (16, 17). However, these surgeon-reported preferences are within the average timing of S2P in many recent analyses (6, 10, 11). Similarly, little deviation was observed in surgeon preferences for non-elective S2P, with the median interval of 4.5 months after Stage 1, a minimum-maximum of 2–7 months, and an IQR of 3.5–4.5 months. Again, the contextualization of this data is difficult given the lack of explicit delineation of elective status.

One of the major findings of this study is that surgeon-reported preferences in the timing of S2P do not differ from the reported timing of S2P in both the CHSS Critical LVOTO registry and in the PHN SVR Trial data set. This represents the first instance of the comparison of surgeon preferences to actual observed clinical practice in the study of LVOTO and single ventricle palliation. In addition, it also indicates that current surgeon preferences do accurately reflect clinical practice from the last decade.

Most importantly, the clear clustering in the timing of S2P and lack of difference in the surgeon-reported preferences indicates a natural standardization in the timing of S2P across the field of congenital heart surgery. This is remarkable given that no high quality evidence, beyond single-institution studies, yet exists to guide decision-making regarding the timing of S2P. This standardization has occurred across very different case mixes, health care systems, regions, nations, and continents. This lack of variability in practice also has implications regarding the ability to detect important differences in the timing of S2P as a potential risk factor for mortality.

Although the medians and interquartile ranges did not differ amongst the three groups, the differences in the minimum and maximum intervals are noteworthy (Figures 2 and 3). These reflect that the true variation in practice is greater than the surgeons' stated preferences, as the timing of S2P in the two clinical data sets demonstrates a much wider range than the surgeons' preferences. Other, "real world" factors, such as intensive care unit bed or operating room availability, may also affect surgeons' ability to perform S2P within their preferred intervals. These factors, for which we were unable to account in this analysis, may play a significant role in the timing of S2P as well. Finally, it must be mentioned that although a surgeon ultimately makes the decision of whether to operate or not, the timing of S2P in the SVR Trial and CHSS data sets likely represents a multi-disciplinary decision in which surgeons, cardiologists, and more collaborate in the management of patients through single ventricle palliation.

Home monitoring programs

The other major finding in this investigation is that the surgeon-reported prevalence of home monitoring programs differs between CHSS and ECHSA members. The adoption and spread of home monitoring has been a major American initiative through the National Pediatric Cardiology Quality Improvement Collaborative, which recently published the three-year results in the use of home monitoring programs. No improvement in mortality was noted during the study period, but differences in weight gain were seen (18). Despite the differences the numbers of home monitoring programs, the timing of S2P did not differ between by society. Again, this "natural standardization" across members of both societies is even more striking when accounting for the differences in the utilization of home monitoring.

Limitations

We acknowledge several important limitations with regard to the study. First, this is an observational survey study in which participation was voluntary, which thereby likely limited the response rate. In addition, since only members of the CHSS and ECHSA were invited to participate, the study only included the opinions of mid- and late-career surgeons. Finally, with regard to the comparison data sets, we are unable to determine if overlap in the patient populations exists. Both studies enrolled during the same time frame. Without unblinding the SVR public data set, there is no way to determine the extent of overlap between the two data sets.

Conclusions

In conclusion, the timing of elective and non-elective S2P did not differ between North American and European centers and between surgeon-reported vs. patient data from two well-known databases. The distribution of the surgeons' preferences appears to demonstrate a natural standardization of practice across the field of congenital heart surgery at Western centers, which is remarkable when taking into account the distinct case mixes, practice patterns, regions, and countries of the participating surgeons. However, further investigation into the effect of the timing of S2P on long term survival through three-stage single ventricle palliation is certainly required. A CHSS study of the optimal timing of S2P is now

underway, motivated by the insight gained here into national and international practice patterns around the timing of S2P

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Abbreviations:

CHSS	Congenital Heart Surgeons' Society
ECHSA	European Congenital Heart Surgeons' Association
LVOTO	Left Ventricular Outflow Tract Obstruction
PHN	Pediatric Heart Network
S2P	Stage-2-Palliation
SVR	Single Ventricle Reconstruction

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1. Does your institution perform Stage 1 operations?	☐ No ☐ Yes - Norwood only ☐ Yes - Hybrid only, ☐ Yes - both Norwood and Hybrid
2. For an uncomplicated patient, what is your personal preference regarding the earliest time after Stage 1 in which you would perform an "elective" Stage 2 operation?	☐ 2 months ☐ 3 months ☐ 4 months ☐ 5 months ☐ 6 months ☐ 7 months ☐ 8 months ☐ 9 months
3. For an uncomplicated patient, what is your personal preference regarding the latest time after Stage 1 in which you would perform an "elective" Stage 2 operation?	☐ 2 months ☐ 3 months ☐ 4 months ☐ 5 months ☐ 6 months ☐ 7 months ☐ 8 months ☐ 9 months
4. Do you typically proceed to "elective" Stage 2 for uncomplicated patients at different times in patients who have undergone Norwood-RVPA vs. Norwood-BT vs. Hybrid?	☐ Not typically ☐ Yes-Norwood-RVPA earliest ☐ Yes-Norwood-BT earliest ☐ Yes-hybrid and comprehensive Stage 2 earliest
5. For a complicated, ill patient, what is your personal preference regarding the earliest time after Stage 1 in which you would perform a Stage 2 operation?	☐ 2 months ☐ 3 months ☐ 4 months ☐ 5 months ☐ 6 months ☐ 7 months ☐ 8 months ☐ 9 months
6. For a complicated, ill patient, what is your personal preference regarding the latest time after Stage 1 in which you would perform a Stage 2 operation?	☐ 2 months ☐ 3 months ☐ 4 months ☐ 5 months
8. If yes, for an uncomplicated patient, at what time point after Stage 1 does your institutional protocol favor elective transition to Stage 2 ?	☐ 2 months ☐ 3 months ☐ 4 months ☐ 5 months ☐ 6 months ☐ 7 months ☐ 8 months ☐ 9 months
9. Does your program have a home monitoring program (home pulse oximetry and/or daily weighing) after Norwood discharge?	☐ No-patients discharged without home monitoring ☐ No-most patients are kept in house until Stage 2 ☐ Yes
10. If yes, does your home monitoring program specify "breach criteria" ?	☐ No ☐ Yes - for hospital admission ☐ Yes - for early progression to Stage 2 ☐ Yes - for both

Figure 1:

Survey of the current preferences in the timing of Stage-2-Palliation (S2P).

Figure 2:

Box and whisker plots comparing the timing of “elective” S2P. Whiskers represent the minimum and maximum values within each data set while the edges of the boxes represent the 25th and 75th percentiles, respectively. The middle lines in the box represent the population median values. The diamonds represent mean values. The medians did not differ, $p=0.19$. CHSS=Congenital Heart Surgeons’ Society Critical Left Ventricular Outflow Tract Obstruction Registry, SVR=Single Ventricle Reconstruction Trial, Surgeon=Surgeon-reported preferences from the survey in this study

Figure 3:

Box and whisker plots comparing the timing of “non-elective” S2P. Whiskers represent the extremes within each data set while the edges of the boxes represent the 25th and 75th percentiles, respectively. The middle lines in the box represent the population median values. The diamonds represent mean values. The medians nearly differed, $p=0.06$.

CHSS=Congenital Heart Surgeons’ Society Critical Left Ventricular Outflow Tract Obstruction Registry, SVR=Single Ventricle Reconstruction Trial, Surgeon=Surgeon-reported preferences from the survey in this study

Table 1:

Survey data and comparisons by society

	All Surgeons	CHSS	ECHSA	P-value*
Interval from Norwood to <i>elective</i> S2P (months)	5 (4.5–6)	4.5 (4–5.5)	4.5 (3–4.5)	0.97
Interval from Norwood to <i>non-elective</i> S2P (months)	4.5 (3.5–5.5)	4.5 (4–5.5)	4.5 (3–5.5)	0.15

* Compared using the Mann-Whitney U test.

Abbreviations: CHSS=Congenital Heart Surgeons' Society, ECHSA=European Congenital Heart Surgeons' Society, S2P=Stage-2-Palliation

Table 2:

Differences in the timing of stage-2-palliation after the type of stage 1 operation

	All Surgeons	CHSS	ECHSA	P-value [*]
No difference timing by type of stage 1 operation	75%	78%	68%	0.50
Norwood-RVPA earliest	7%	5%	12%	0.50
Norwood-BT earliest	10%	10%	8%	0.50
Hybrid earliest	8%	7%	12%	0.50

* Compared using Fisher's exact test.

Abbreviations: CHSS=Congenital Heart Surgeons' Society, ECHSA=European Congenital Heart Surgeons' Society, RVPA=right-ventricle-to-pulmonary artery conduit, BT=Blalock Taussig shunt

Table 3:

Survey data and comparison with other data sets

	Surgeon Preferences	CHSS Critical LVOTO	SVR Trial	P-value [*]
Interval from Norwood to <i>elective</i> S2P (months)	5 (4.5–6)	5.1 (4.2–6.2)	5.3 (4.4–6.1)	0.19
Interval from Norwood to <i>non-elective</i> S2P (months)	4.5 (3.5–5.5)	4.6 (3.7–5.5)	4.2 (3.2–5.1)	0.06

* Compared using the Kruskal-Wallis test.

Abbreviations: CHSS=Congenital Heart Surgeons' Society, ECHSA=European Congenital Heart Surgeons' Society, LVOTO=Left Ventricular Outflow Tract Obstruction, SVR=Single Ventricle Reconstruction, S2P=Stage-2-Palliation

Table 4:

Program characteristics

	All Surgeons	CHSS	ECHSA	P-value*
Institutional home monitoring program	75%	90%	38%	< 0.0001
Breach criteria included in home monitoring program				0.62
No	17%	18%	11%	
Yes, for admission	50%	46%	67%	
Yes, for early S2P	0%	0%	0%	
Yes, both	33%	36%	22%	
Protocol for elective progression to S2P	27%	20%	44%	0.05
3 months after Norwood	14%	8%	20%	0.18
4 months after Norwood	36%	50%	20%	0.18
5 months after Norwood	36%	42%	30%	0.18
6 months after Norwood	14%	0%	30%	0.18

* Compared using Fisher's exact test.

Abbreviations: CHSS=Congenital Heart Surgeons' Society, ECHSA=European Congenital Heart Surgeons' Society, S2P=Stage-2-Palliation