Practice variation using the hybrid stage I procedure in congenital heart disease: Results from a national survey

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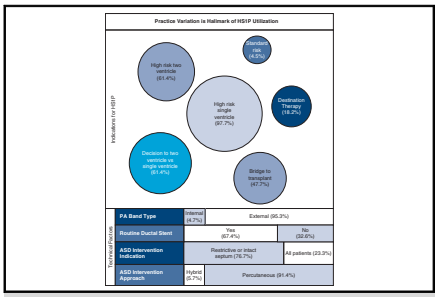
ABSTRACT

Objectives: Hybrid stage I palliation has been used in many clinical scenarios including initial palliation in single ventricle heart disease, a bridge to biventricular repair, a bridge to transplant, and as a destination therapy. There is considerable hybrid stage I palliation practice variation, which we aimed to better understand in this study.

Methods: Survey-based assessment of practice variation related to hybrid stage I palliation was sent to congenital heart centers across the United States and Canada.

Results: Of the 106 centers surveyed, responses were received from 54 centers (50.9%). Of respondents, 45 centers perform hybrid stage I palliation. Centers most commonly (97.7%) perform hybrid stage I palliation on "high-risk" patients with single ventricle heart disease. Regarding the technical aspects of hybrid stage I palliation, most centers (95.3%) accomplish restrictive pulmonary blood flow using pulmonary artery bands and primarily use changes in oxygen saturation (34.1%) to identify appropriate restriction. Ductal stents are most often used (67.4%) to maintain ductal patency. Only 10 centers (23.3%) routinely enlarge the atrial septal defect. Indications for atrial septal defect intervention varied widely. Most centers (71.9%) discharge patients home to follow with a formal "interstage" program.

Conclusions: There is significant variation in practice patterns for hybrid stage I palliation indications, technical aspects, and postoperative care. Therefore, generalizability of single-center studies on outcomes after hybrid stage I palliation is limited. Future multicenter studies are needed to best delineate which patients benefit most from hybrid stage I palliation and to further define optimal approaches to caring for these patients. (JTCVS Open 2024;21:248-56)



Survey responses and HS1P volume by center.

CENTRAL MESSAGE

There is considerable practice variation in the use and performance of HS1P, making meaningful retrospective analysis of HS1P outcomes difficult.

PERSPECTIVE

HS1P has gained popularity as an alternative to the Norwood procedure and has been applied to other congenital heart diseases as a bridge to biventricular repair and heart transplant. Despite its increasing practice, there is significant variation in practice patterns for HS1P indications, technique, and postoperative care, making it difficult to determine which patients most benefit from this palliative strategy.

Hybrid stage I palliation (HS1P) is an alternative to the Norwood operation for patients with single ventricle (SV) heart disease. It is also used for patients with other congenital heart diseases, including those who may ultimately undergo biventricular repair[1,2] or heart transplant,[3-7] and sometimes as a destination therapy. In principle, HS1P consists of maintaining arterial ductal patency, restricting pulmonary artery (PA) blood flow, and creating/maintaining a nonrestrictive atrial septal defect (ASD). HS1P avoids the need for cardiopulmonary bypass and therefore may have

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The Institutional Review Board or equivalent ethics committee of the University of Michigan did not approve this study because no patient data were collected, and no patients were contacted. Patient written consent for the publication of the study was not received because no patients were contacted or involved in the study.

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Abbreviations and Acronyms
ASD = atrial septal defect
HS1P = hybrid stage 1 palliation
PA = pulmonary artery
PBF = pulmonary blood flow
SV = single ventricle

potential to be a lower-risk option in certain patients. There is some evidence that it may lessen initial 30-day mortality[8,9] and a suggestion that neurological outcomes could be improved due to avoidance of alterations in cerebral perfusion during arch reconstruction.[10] However, HS1P has not proven to be clearly superior to traditional surgical strategies. To date, there is conflicting evidence regarding which patients may benefit from HS1P.[11] Because of this lack of clarity, there are significant differences in clinical indications among centers and wide variability in institutional preferences regarding technique and postprocedural care. This practice variation has made meaningful retrospective analysis of HS1P outcomes difficult. In this study, we collected survey data from North American congenital heart centers to more completely describe HS1P practice variation than has been done in prior studies.

MATERIAL AND METHODS

The Institutional Review Board or equivalent ethics committee of the University of Michigan did not approve this study because no patient data were collected and no patients were contacted. Patient written consent for the publication of the study was not received because no patients were contacted or involved in the study. A cross-sectional survey study examining HS1P practice variation was performed. The survey was designed to collect data within 3 domains: patient selection, technical aspects of HS1P, and post-HS1P patient management (Table 1). The survey was sent electronically via REDCap with anonymized responses to all North American congenital heart centers and addressed to the "chief" of congenital heart surgery as identified using the "Hospital Directory from Congenital Cardiology."[12] Email addresses were identified via public directories. We requested the survey be completed by the surgeon most closely involved with HS1P at their institution, and if there is not such a surgeon, that the chief of congenital cardiac surgery complete the survey. Survey responses were summarized as frequency with percentage (%).

RESULTS

Surveys were sent to 106 centers, and responses were received from 54 centers (50.9%) (Figure 1). Of the centers surveyed, 45 centers perform HS1P. The majority (77.8%) of them perform 5 or less per year.

Patient Selection

To understand HS1P indications, centers were asked to choose the most common situations in which it is used (multiple selections were allowed) (Table 1). Centers most commonly answered that they perform HS1P on "high-risk" patients with SV heart disease (97.7%) (Figure 2). Twenty-seven centers (61.4%) perform HS1P on patients with biventricular circulation and 27 centers (61.4%) use HS1P as a bridge to determine biventricular repair candidacy in patients with borderline left heart structures. Only 2 centers (4.5%) routinely perform HS1P on all SV patients regardless of risk stratification. Additional indications for HS1P included bridge to transplant (47.7%), normal cardiovascular anatomy with severely depressed ventricular function (20.5%), and as a destination (palliative) therapy (18.2%).

High-risk SV determination was variable among centers. The most commonly cited reasons for "high-risk" designation included prematurity (88.4%), low birth weight (79.1%), noncardiac malformations (69.8%), and ventricular dysfunction (69.8%) (Figure 3). The most common "high-risk" indications for biventricular circulation were prematurity (77.8%), noncardiac malformations (66.7%), and low birth weight (59.3%) (Figure 4). Among biventricular lesions for which HS1P was used, the 2 most common types were Shone's complex (66.7%) and interrupted aortic arch (63%) (Figure 5).

Technical Aspects

Respondents were asked to choose all locations where they completed HS1P, and most used more than 1 location with 55.8% using a hybrid operating room, 44.2% using the catheterization laboratory, and 37.2% using a general operating room. Eighteen centers (41.9%) have a dedicated surgeon for HS1P. Likewise, 24 centers (55.8%) have a dedicated interventionalist for HS1P. Fifteen centers (34.9%) have a dedicated surgeon/interventionalist pair who complete all HS1P procedures. Most respondents (60%) have been performing HS1P for 10 years or more. Ten centers (22.2%) have been performing HS1P for 6 to 10 years, 7 centers (15.6%) for 3 to 5 years, and 1 center (2.2%) for 0 to 2 years.

Among the more specific technical aspects of the procedure, centers were surveyed on mechanisms for pulmonary blood flow (PBF) restriction, maintenance of arterial ductal patency, and ASD intervention (Figure 6). Most centers (95.3%) accomplish restrictive PBF using PA bands fashioned from Gore-Tex tube grafts and primarily use changes in oxygen saturation (34.1%) to identify appropriate restriction, although methods were variable.

Ductal stents are most often used (67.4%) to maintain ductal patency, and these are nearly always (89.7%) implanted as part of the HS1P procedure when anatomically feasible. The most common (82.8%) approach for ductal stent implantation was via a sheath placed directly in the main PA. A minority (17.2%) of centers used an antegrade approach via the femoral vein or retrograde approach via the femoral artery. Additionally, the majority (62.1%) of centers use a self-expanding ductal stent.

TABLE 1. Hybrid stage 1 palliation operative/procedural technique

Mechanism for PBF restriction		Mechanism to maintain ductal patency		ASD intervention	
Approach:		**Routinely implant ductal stent?**		**Intervention indicated if the ASD is:**	
Internal flow restrictors:	2/43 (4.7%)	Yes:	29/43 (67.4%)	Intact or highly restrictive:35/43 (81.4%)	
PA band:	41/43 (95.3%)	No:	14/43 (32.6%)	Restrictive or small:31/43 (72.1%)	
				Routinely enlarge all ASDs:10/43 (23.3%)	
PA band material:		**When is this typically accomplished?**		**Intact/highly restrictive ASD**	**Restrictive/Small ASD**
Gore-Tex patch:	6/41 (14.6%)	As part of HS1P	26/29 (89.7%)	Highly restrictive defined as mean echo gradient of…	Restrictive/small ASD defined as…
Gore-Tex tube graft:	34/41 (82.9%)	Separate percutaneous procedure:	3/29 (10.3%)	0-3 mm Hg: 1/35 (2.9%)	0-3 mm Hg: 0/30 (0.0%)
Silk suture:	0/41 (0.0%)			4-6 mm Hg: 3/35 (8.6%)	4-6 mm Hg: 6/30 (20.0%)
Other:	3/41 (7.3%)			7+ mm Hg: 15/35 (42.9%)	7+ mm Hg:11/30 (36.7%)
Appropriate PBF restriction primarily determined by:		**Approach for stent placement:**		Gradient not used: 1/35 (2.9%)	Other: 2/30 (6.7%)
SBP change:	2/41 (4.9%)	Via sheath in MPA:	24/29 (82.8%)	Unsure: 13/35 (37.1%)	Size of ASD by echo: 12/31 (38.7%)
SpO2 change:	14/41 (34.1%)	Antegrade via femoral vein:	3/29 (10.3%)	No answer: 2/35 (5.7%)	Hypoxia thought to be related to ASD size: 19/31 (61.3%)
Direct pressure measurement:	2/41 (4.9%)	Retrograde via femoral artery:	2/29 (6.9%)		
Standard band diameter:	10/41 (24.4%)				
Echo measure/ gradient:	7/41 (17.1%)				
Other:	6/41 (14.6%)				
		Ductal stent type		**When is ASD intervention performed?**	**When is ASD intervention performed?**
		Self-expanding:	18/29 (62.1%)	Before HS1P: 18/35 (51.4%)	Before HS1P: 16/31 (51.6%)
		Balloon expandable:	11/29 (37.9%)	During HS1P: 11/35 (31.4%)	During HS1P: 12/31 (38.7%)
				After HS1P but before next palliation: 5/35 (14.3%)	After HS1P but before next palliation: 2/31 (6.5%)
				No answer: 1/35 (2.9%)	No answer: 1/31 (3.2%)

(Continued)

TABLE 1. Continued

Mechanism for PBF restriction	Mechanism to maintain ductal patency	ASD intervention	
		Approach for ASD intervention: 2/35 (5.7%) use a per atrial approach with:	**Approach for ASD intervention:** 2/31 (6.5%) use a per atrial approach with:
		ASD Stent: 0/2	ASD Stent: 1/2 (50%)
		Static/cutting balloon: 2/2 32/35 (91.4%) use a percutaneous approach with:	Static/cutting balloon: 1/2 (50%) 27/31 (87.1%) use a percutaneous approach with:
		ASD Stent: 13/32 (40.6%)	ASD Stent: 10/27 (37%)
		Balloon septostomy: 19/32 (53.4%)	Balloon septostomy: 15/27 (55.6%)
		0/35 perform an atrial septectomy	1/31 (3.2%) perform an atrial septectomy

ASD, Atrial septal defect; *PA*, pulmonary artery; *HS1P*, hybrid stage 1 palliation; *PBF*, pulmonary blood flow; *MPA*, main pulmonary artery.

Only 10 centers (23.3%) routinely enlarge the ASD before or at the time of HS1P. Indications for ASD intervention varied widely. Most centers (61.3%) defined an ASD as being "restrictive" or "small" if there was hypoxia thought to be related to the ASD size, which would be an indication for intervention. Although there is no consensus definition for "highly restrictive" ASD, most centers considered a mean echo gradient of 7 mm Hg or greater to be "highly restrictive." The timing of ASD intervention is detailed in Figure 6 and varied by indications for ASD intervention. A percutaneous approach was most often used.

Post–Hybrid Stage 1 Palliation Management

Most centers (90.7%) have a formal "interstage" program with protocolized follow-up. Postprocedural monitoring varies, but the majority of centers (93.0%) performed a weekly echo while in the intensive care unit, weekly (44.2%) or biweekly (37.2%) while in general

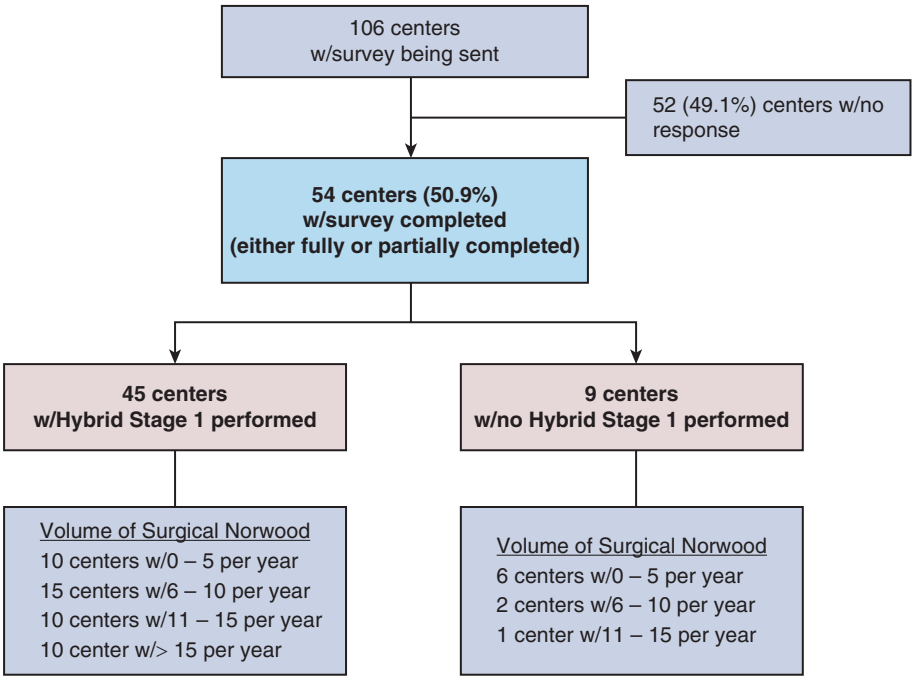

FIGURE 1. Survey responses.

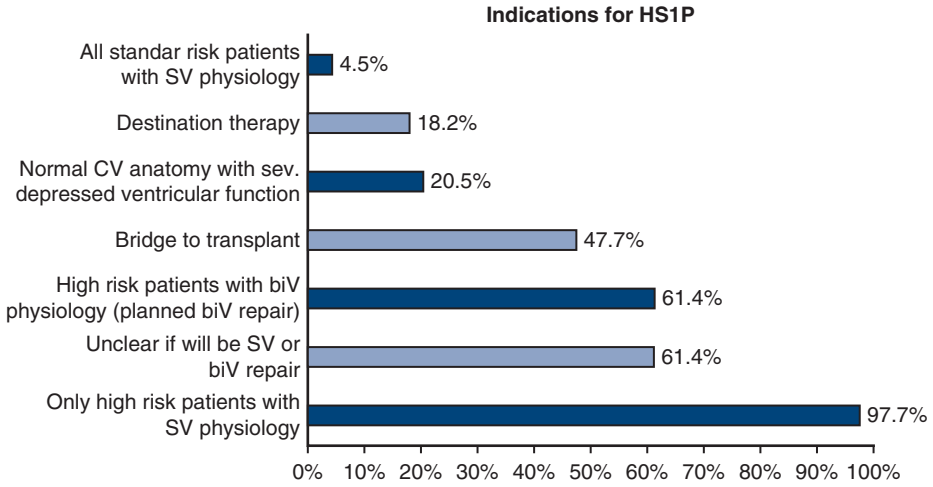

FIGURE 2. Indications for HS1P. *HS1P*, Hybrid stage 1 palliation; *SV*, single ventricle; *CV*, cardiovascular; *biV*, biventricular.

care, and biweekly (56.3%) while outpatient. Most centers (74.4%) discharge patients who are ready before their next surgical procedure. Eighteen centers (56.3%) follow HS1P patients exclusively at their center, and a portion (43.8%) manage care in unison with a referring/outside cardiologist.

For patients with SV physiology, 29 centers (70.7%) perform a Norwood operation as the next palliative stage, whereas 12 centers (29.3%) perform a comprehensive stage 2 procedure. Goal timing for a Norwood procedure was most commonly 4 to 6 weeks after the HS1P (44.8%). Most centers (66.7%) that performed a comprehensive stage 2 aimed for 5 to 6 months after the HS1P. For patients with biventricular circulation, definitive repair was most often accomplished 5 to 8 months after HS1P (55.6%).

DISCUSSION

We report the survey results from 54 congenital heart centers regarding HS1P practice variation. In recent years, the HS1P has been adopted as a palliative strategy for a wider range of congenital heart diseases, both SV and

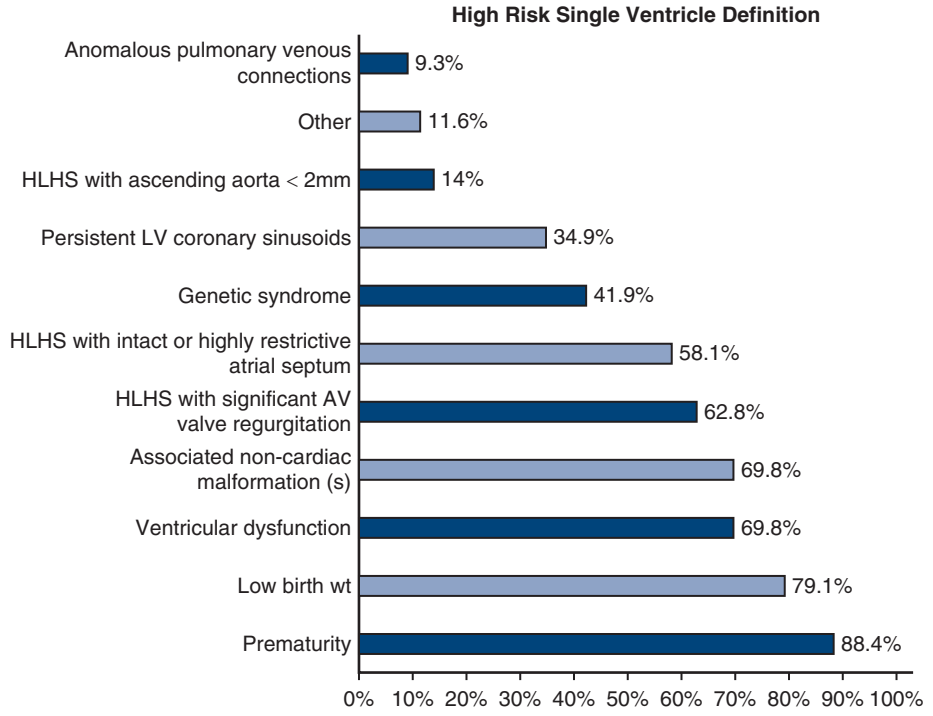

FIGURE 3. High-risk SV definition. *HLHS*, Hypoplastic left heart syndrome; *LV*, left ventricle; *AV*, aortic valve.

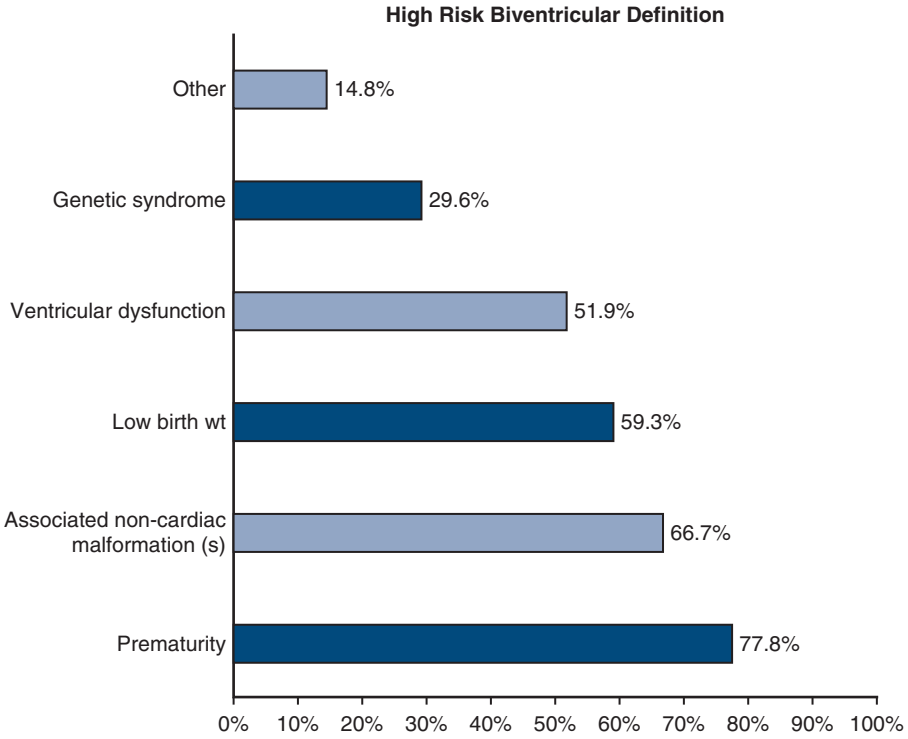

FIGURE 4. High-risk biventricular circulation definition.

various forms of biventricular heart disease.[10] Despite its increasing use, there is no generalized consensus for HS1P indications, technique, or postoperative care, which has made it difficult to evaluate patient outcomes and determine which patients may benefit most from this approach.

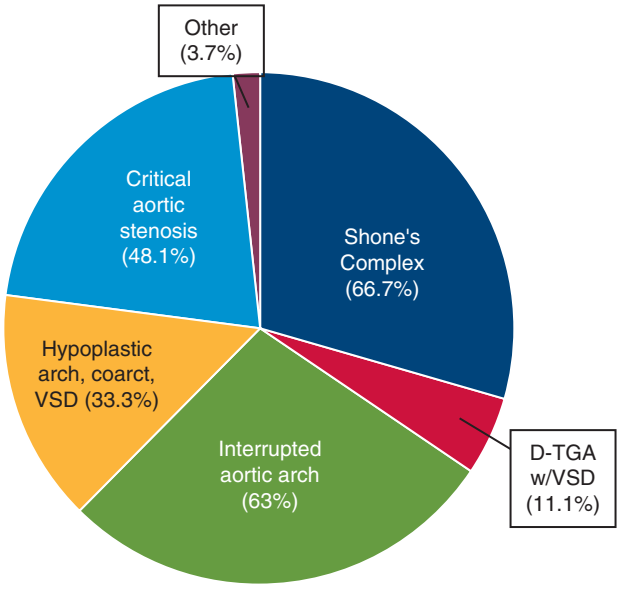

FIGURE 5. Biventricular lesion types. *D-TGA*, Dextro transposition of the great arteries; *VSD*, ventricular septal defect.

We aimed to detail practice variation in an effort to guide future study.

Patient Selection

Among survey respondents, the majority (83.3%) of centers perform HS1P, although only 2 centers routinely perform HS1P on all SV patients. Most reserve this procedure for "high-risk" SV patients. Data remained mixed on survival benefit for HS1P over a traditional Norwood procedure,[8-11,13,14] and although some studies suggest that HS1P imparts a modest survival benefit for "high-risk" SV patients,[15-21] the data remain unclear. Historical surgical Norwood outcomes also likely play a role in a center's decision for palliation type where HS1P may be an appealing alternative in an effort to increase stage 1 survival. However, future correlation of institution-specific Norwood outcomes and stage 1 practice patterns would be necessary to fully understand this.

In our study, "high-risk SV physiology" was the most common indication for HS1P. Established mortality risk factors in SV heart disease include birth weight less than 2.5 kg, prematurity (<34 weeks' gestational age), less than a 2-mm ascending aorta, poor ventricular function, tricuspid regurgitation, intact or restrictive atrial septum, serious noncardiac malformations, and genetic abnormalities[10,13,22-26] in addition to cardiac anomalies including interrupted aortic arch, anomalies of pulmonary venous connections (including total anomalous pulmonary venous

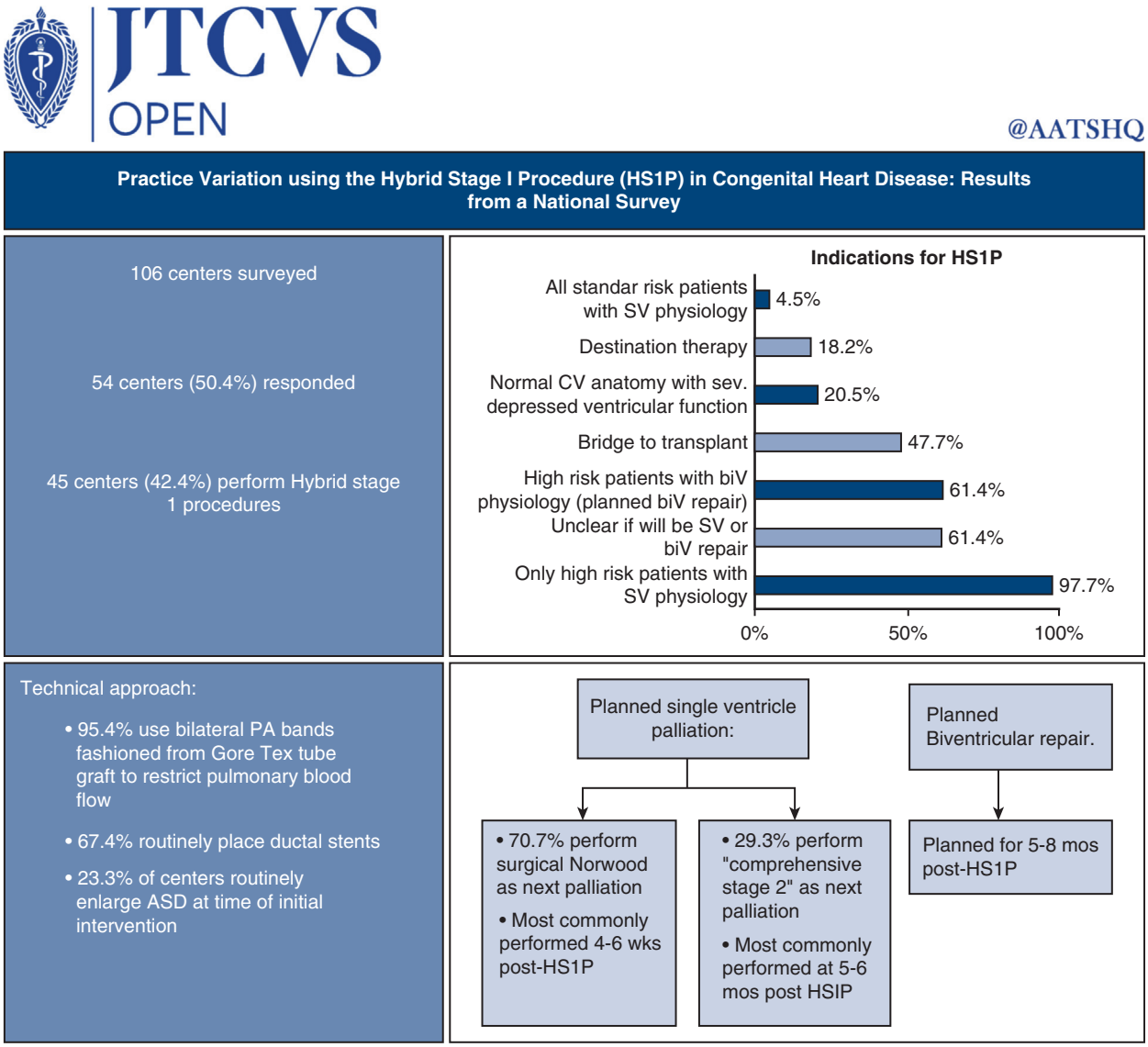

FIGURE 6. Graphical Abstract. *HS1P*, Hybrid stage 1 palliation; *SV*, single ventricle; *CV*, cardiovascular; *biV*, biventricular; *PA*, pulmonary artery; *ASD*, atrial septal defect.

connection), obstruction to pulmonary venous drainage, and atrioventricular valvar regurgitation.[22,23] Despite these established risk factors, there is no consensus definition for "high-risk" SV patients as has been previously noted by Geoffrion and colleagues,[24] and "high-risk" determination in our survey was quite variable. Among respondents, there is general agreement that prematurity constitutes "high-risk" SV patients who may be suitable for HS1P (88.4% of centers). Other risk factors were quite variable and highlight the need for consensus definitions of "high-risk" SV physiology, which would facilitate future study to determine HS1P benefit over the standard surgical Norwood approach.

The majority of centers also use HS1P in certain "high-risk" biventricular lesions as a bridge to eventual biventricular repair or as a means to defer decision making regarding ultimate repair in patients with borderline left heart structures, which is a well-described strategy.[6,25,26] Indications for HS1P in "high-risk" biventricular physiology are similar to those in the SV group and most commonly include prematurity (77.8%) and low birth weight (59.3%), but are otherwise variable. Again, uniform indications for HS1P in patients with 2 ventricles or borderline left-sided structures would facilitate future study of this approach.

Technical Aspects

As with indications for HS1P, the technique also differs widely. The procedure has 3 primary goals: achieving

adequate PBF restriction, maintaining ductal patency, and ensuring unobstructed pulmonary venous return. Precise PBF restriction to balance pulmonary and systemic circulation and protect the pulmonary vascular bed from elevated pressure/flow is challenging, particularly in the SV population, and multiple techniques to ensure PBF restriction are described. Common approaches to determine PBF restriction adequacy include changes in systolic blood pressure or oxygen saturation, direct pressure measurement using a pressure sensing wire, echo Doppler gradient, and using standardized band sizes based on patient size.[27,28] Among those surveyed, PBF restriction was almost exclusively accomplished with bilateral PA bands fashioned from Gore-Tex tube graft. However, the mode of ensuring appropriate restriction is not nearly as uniform among centers. Oxygen saturation change was most frequently used (34.1%) to determine PBF restriction adequacy, with a wide variability among other parameters.

Maintenance of ductal arterial patency can be accomplished in 1 of 2 ways: arterial ductal stent or maintenance on a prostaglandin infusion. Both strategies have their advantages and disadvantages. Ductal stent implantation assumes the risk of procedural complications and may put patients at risk for reverse coarctation in the context of a diminutive transverse aorta. However, a ductal stent generally achieves a more reliable source of systemic perfusion and allows patients to be off of an intravenous prostaglandin infusion with the opportunity for discharge home. Alternatively, maintaining patients on a prostaglandin infusion removes procedural risk associated with stent placement and lessens the risk of reverse coarctation, although it is associated with various medication side effects, the perils of long-term vascular access, and the need to remain in the hospital until more definitive palliation. The majority of centers surveyed (67.4%) routinely place a ductal stent and 32.6% of centers opt to maintain patients on a prostaglandin infusion. For centers that routinely place ductal stents, there also remains variability in the use of balloon-expandable versus self-expanding stents, although some data would suggest that self-expanding stents have a better safety profile.[29]

Relief of atrial-level restriction is crucial in patients with HS1P; however, intervention can be technically challenging and is associated with a mortality risk as high as 15%.[30] Among our respondents, there are variable approaches to ASD intervention, presumably due to its complexity and risk. Nearly all centers use a percutaneous approach for ASD intervention. Just 23.3% of centers routinely enlarge ASDs in all HS1P patients. Interestingly, only 81.4% of centers reported that they intervene on an intact atrial septum or a highly restrictive ASD, which may speak to the lack of clarity surrounding definitions for this pathology. Indications to intervene on the ASD remain imprecise, with the most commonly chosen indication being hypoxia. There is no consensus on the echocardiographic definition of ASD restriction, although most centers considered a mean gradient of 7 mm Hg or greater to meet criteria.

Post–Hybrid Stage 1 Palliation Care

Although indications for HS1P and technique are quite variable, there is more uniformity across centers for follow-up of this high-risk group with most having a formal "interstage" program with protocolized monitoring. These programs have become commonplace among congenital heart centers due to an impressive survival benefit in SV patients undergoing a Norwood operation.[31] Strategies for subsequent surgeries and timing of these interventions were center specific, although most pursue a Norwood operation 4 to 6 weeks after initial HS1P.

Limitations

There are a number of limitations to this survey-based study. First, we had a limited number of responses with just over half of the queried centers filling out the survey. Additionally, this survey may have been affected by the difficulty of answering generalized questions regarding a treatment strategy for complex and diverse congenital heart disease, which often does not lend itself well to a standardized approach.

CONCLUSIONS

There is a significant variation in practice patterns for HS1P regarding indications, technical aspects, and postoperative care. Generalizability of single-center studies on patient outcomes after HS1P is limited and would be greatly enhanced with consensus definitions for "high-risk" SV patients to better understand indications. Lack of standardization regarding patient selection and procedural technique has limited meaningful assessment of the merits of HS1P, and the lack of clear data likely has contributed to the varying outcomes of the procedure thus far. Although there are many inherent challenges to performing multicenter studies related to HS1P, this will be necessary to best define which patients truly benefit most from this approach and how to ideally manage them.

Conflict of Interest Statement

J.D.Z. is a consultant for Medtronic Inc and Gore Medical, and serves on the Data Safety Monitoring Board for Encore Medical. All other 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.

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