

# Improved outcomes with the comprehensive stage 2 procedure after an initial hybrid stage 1

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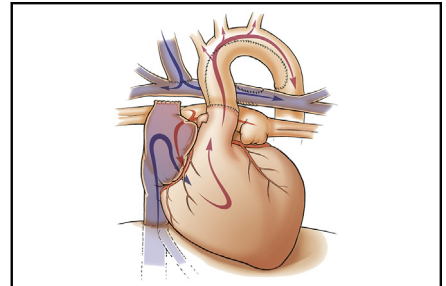
## ABSTRACT

**Objective:** To report our improving institutional experience with the hybrid alternative surgical strategy for the management of hypoplastic left heart syndrome, in which hybrid stage 1 is followed by a comprehensive stage 2 procedure (removal of patent ductus arteriosus stent and pulmonary artery [PA] bands, aorta and PA reconstruction, Damus–Kaye–Stansel, atrial septectomy, Glenn).

**Methods:** In this Institutional Review Board–approved retrospective review of all patients undergoing a comprehensive stage 2 procedure between January 2002 and December 2014, data were compared between the pre-protocol group (n = 64; January 2002 to March 2010) and the post-protocol group (n = 55; March 2010 to December 2014). These 2 groups flank the implementation of a perioperative management protocol to prevent PA thrombosis.

**Results:** Pre-protocol mortality was 19% (12 of 64), with the most common mode of death involving PA thrombosis in at least 7 patients, with an urgent indication for surgery and age as contributing factors. Care modifications instituted in March 2010 included avoidance of procedures on an emergent basis or in patients aged <3 months, use of a systemic PA shunt in cases of too-small superior vena cava and/or PA, completion angiogram with a low threshold for intraoperative stenting, and postoperative anticoagulation therapy for 6 weeks. There was a significant decrease in mortality (2 of 55; 4%;  $P = .01$ ), PA thrombosis (0 of 55; 0%;  $P = .01$ ), and use of extracorporeal membrane oxygenation (0/55 [0%] compared with 7 of 64 [11%];  $P = .01$ ) after protocol implementation.

**Conclusions:** Despite the technical challenges of the comprehensive stage 2 procedure, excellent outcomes are attainable. Experience coupled with an internal quality review drove the implementation of a successful perioperative management protocol. (*J Thorac Cardiovasc Surg* 2016;151:424-9)



Comprehensive stage 2 procedure.

### Central Message

Significantly improved outcomes for the comprehensive stage 2 procedure following an initial hybrid stage 1 procedure have been demonstrated with the implementation of a perioperative protocol focused on eliminating pulmonary artery thrombosis.

### Perspective

The hybrid approach has emerged as an alternative surgical strategy for the management of hypoplastic left heart syndrome. A hybrid stage 1 is followed by a comprehensive stage 2 procedure. This is a challenging new procedure with very little published outcome data. We report our improving institutional experience.

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The hybrid approach has emerged as an alternative surgical strategy for the management of hypoplastic left heart syndrome (HLHS).<sup>1-4</sup> The initial hybrid stage 1 combines the surgical placement of branch pulmonary

artery (PA) bands with transcatheter placement of a patent ductus arteriosus (PDA) stent and balloon atrial septostomy. The subsequent surgery, often referred to as a comprehensive stage 2 or combined Norwood 1 and 2, involves removal of the PA bands with possible PA reconstruction, removal of the PDA stent with aortic arch reconstruction, a Damus–Kaye–Stansel connection of the aortic and PA roots, a bidirectional superior cavopulmonary connection, and an atrial septectomy

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**Abbreviations and Acronyms**

ECMO	= extracorporeal mechanical oxygenation
HLHS	= hypoplastic left heart syndrome
PA	= pulmonary artery
PDA	= patent ductus arteriosus
SVC	= superior vena cava

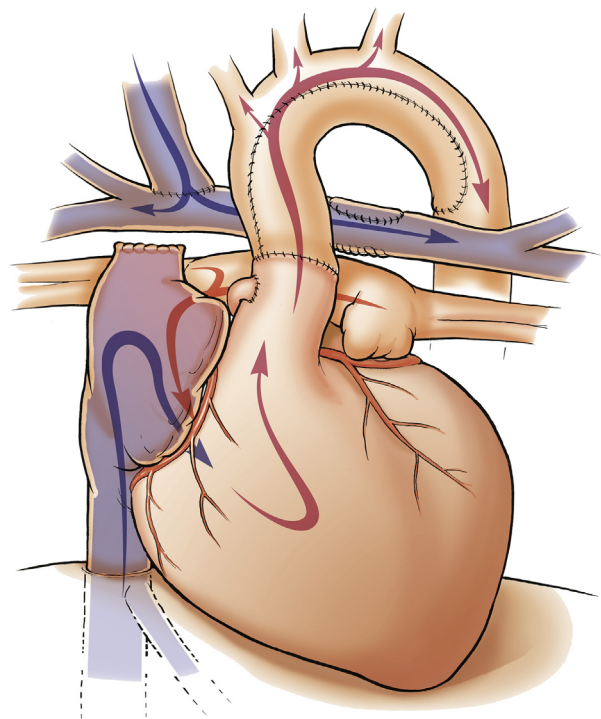
(Figure 1). This challenging new procedure is critical to the overall success of the hybrid approach. Here we share our institutional experience with the comprehensive stage 2 procedure, with attention given to our significantly improved outcomes after the institution of a perioperative management protocol focused on reducing or eliminating PA thrombosis.

**METHODS**

This was an Institutional Review Board–approved retrospective review of prospectively collected data on all patients undergoing a comprehensive stage 2 procedure between January 2002 and December 2014. The patients were separated into 2 chronological cohorts based on the implementation of a new perioperative management protocol: pre-protocol, from January 2002 to March 2010 ( $n = 64$ ) and post-protocol, from March 2010 to December 2014 ( $n = 55$ ). Excluded from this analysis were any patients palliated with a hybrid stage 1 procedure who then underwent a 2-ventricle repair.

In early 2010, as part of our Heart Center's quality improvement initiative, we evaluated the causes of death in patients who had undergone a comprehensive stage 2 procedure. This analysis revealed that the most common mode of death involved the development of PA thrombosis during the postoperative period. Further analysis of this subgroup of patients who developed a confirmed PA thrombus did not reveal any predictive perioperative factors. Preoperative factors assessed included diagnosis, age, weight, saturation, comorbid diagnoses, ventricular function and/or tricuspid regurgitation, and characteristics of flow through the PA bands and through the PDA stent. Intraoperative factors considered included bypass and cross-clamp times; PA and aortic arch reconstruction techniques; immediate postoperative bleeding with resultant treatment, including any use of activated factor VII; immediate cardiac function; oxygen saturation; and inotrope use. Initial postoperative intensive care unit factors considered included cardiac/pulmonary/renal function, intubation time, fluid balance, inotrope score, and use of anticoagulation. Again, no preoperative, intraoperative, or postoperative factor was predictive of or associated with the development of a PA thrombus, yet the consequence of its development was severe. Therefore, we initiated a preventive strategy in March 2010, as outlined in Table 1. The goal of this protocol was to prevent the development of PA thrombus formation with its significant impact on morbidity and mortality.

Other measures identified from the quality initiative review of the pre-protocol patients were also instituted at this time. These included refraining from performing a comprehensive stage 2 procedure in patients aged <3 months or as an emergent procedure in decompensating patients who had undergone a hybrid stage 1 procedure. In addition, instead of proceeding with the standard comprehensive stage 2 procedure as described above in all patients regardless of intraoperative findings, in patients in whom the PA and/or superior vena cava (SVC) was too small to allow safe creation of a reliable cavopulmonary



**FIGURE 1.** Completed comprehensive stage 2.

connection, if necessary the procedure was modified, with the use of a systemic-to-PA shunt as a source of pulmonary blood flow.

Eight patients in the pre-protocol group required hospital admission immediately before undergoing the comprehensive stage 2 procedure. Reasons for admission included vomiting and feeding issues in 3 patients, decreased function and preoperative inotropic support in 2 patients, no discharge from the hospital in 1 patient, and cyanosis in 2 patients.

Finally, although the general operative procedure was the same in the 2 groups, performed on bypass with no use of circulatory arrest,<sup>5,6</sup> the technique was modified for some patients in the post-protocol group. In these patients, the entire operation was performed on bypass with no cross-clamping or circulatory arrest, using an additional aortic root cannula coupled with antegrade cerebral perfusion.

Categorical data were compared using Fisher's exact test. Continuous data were analyzed using the Mann-Whitney *U* test or a 2-tailed *t* test depending on the results of the D'Agostino and Pearson omnibus normality test. The effects of time and experience were assessed using logistical regression with Firth's penalized likelihood to account for rare events. A *P* value < .05 was considered significant in all analyses.

**RESULTS**

Twelve patients died before implementation of the protocol, with most deaths related to the morbid consequences of a PA thrombus. PA thrombus was confirmed in 7 patients by catheterization and suspected in 2 others (Figure 2). A detailed analysis of these patient's perioperative characteristics revealed no predictive factor for PA thrombus formation. The next most common mode of death involved emergent or early surgery

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