W(h)ither the hybrid? Up the “Slope of Enlightenment”

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As noted by the Gartner Group, technologic innovations follow a common pattern of uptake in the marketplace.¹ Initially, a “Technology Trigger” is hailed as a potential breakthrough for a vexing problem. Glowing reports trigger increasing interest, and a publicity buzz leads to the “Peak of Inflated Expectations.” Soon thereafter, early success stories begin to be met with reports of failure. Enthusiasm wanes, and the innovation falls into the “Trough of Disillusionment,” where the shortcomings of the innovation become ever more apparent. Popularity tends to wither—however, a few persistent groups continue to refine the innovation. More resilient beneficial aspects are identified, and through the persistence of these groups, the innovation begins to move up the “Slope of Enlightenment.” Clarity develops as the marketplace identifies positive aspects of the innovation within the confines of specific niches. The innovation enters the “Plateau of Productivity,” where mainstream adoption occurs within newly established niches.

Hybrid management for single-ventricle palliation has followed a similar pattern. Originally described in 1993 by Gibbs and colleagues,² adaptation of bilateral pulmonary artery banding and ductal stenting as an alternative to Norwood-based palliation for patients with hypoplastic left heart syndrome (and for those with single-ventricle variants) was a technologic trigger that gained popularity through pioneering work from the groups in Giessen,³ Columbus,⁴ and Chicago.⁵ Like many programs, we joined in the exciting conceptual approach of hybrid management as an alternative to the Norwood procedure. Many subsequent reports, however, have demonstrated that overall surgical outcomes for patients managed with the hybrid and Norwood strategies are relatively similar, and neither approach currently has demonstrated a strong beneficial survival advantage for patients with “standard”

single-ventricle physiology. The contribution of the hybrid strategy to our surgical armamentarium, however, is still becoming manifest as we march up the Slope of Enlightenment to clarify the value of the hybrid strategy in many potential niches.

In this issue of the *Journal*, Karamlou and colleagues⁶ attempt to describe patterns of adoption of the hybrid strategy through analysis of the Society of Thoracic Surgeons database. Difficulties encountered by the group include the lack of a specific variable for bilateral pulmonary artery banding in the database. To work around this problem, Karamlou and colleagues⁶ had to use a complex set of criteria to discriminate patients presumed to have undergone bilateral pulmonary artery banding. Furthermore, because the data set does not include a variable encoding ductal stenting, the timing of associated ductal stenting is not specified—and the ductal stenting may occur at the time of pulmonary artery banding, at a subsequent procedure, or not at all for patients maintained on prostaglandin infusions. Despite these logistic problems, Karamlou and colleagues⁶ have succeeded in demonstrating that patients selected for hybrid management have a higher profile of preoperative risk factors than do those undergoing Norwood procedures. Interestingly, centers with lower volumes are more likely to be high adopters of the hybrid procedure. It will be important for Karamlou and colleagues⁶ to repeat this study in several years to identify trends in the adoption of the hybrid strategy. Is the hybrid strategy on the upswing or downswing in terms of overall use? Will the greater surgical simplicity of the stage I hybrid procedure translate into greater ability to obtain outcomes in low-volume institutions that are comparable to those in large-volume institutions?

Although initial reports focused on the use of the hybrid strategy as an alternative to the Norwood strategy for routine single-ventricle palliation, niches are rapidly developing in which the Hybrid strategy can be used. Borderline left-sided hypoplasia presents an opportunity to use the hybrid strategy to maximize the potential for obtaining a 2-ventricle circulation. The pioneering group in Giessen, Yerebakan and associates,⁷ has demonstrated the utility of the hybrid strategy for palliation in neonates with hypoplastic left heart structures, followed by subsequent 2-ventricle palliative procedures. Although Yerebakan and associates⁷ demonstrate that the approach is highly successful in a subset of patients with hypoplastic left heart structures, the selection criteria for entry into this 2-ventricle pathway are somewhat unclear. An undefined subset of patients in the neonatal period might have

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Disclosures: Author has nothing to disclose with regard to commercial support.

Received for publication Oct 28, 2014; accepted for publication Oct 29, 2014.

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J Thorac Cardiovasc Surg 2015;149:7-8

0022-5223/\$36.00

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<http://dx.doi.org/10.1016/j.jtcvs.2014.10.116>

been considered as biventricular candidates but failed to elicit sufficient confidence by the surgical group at the time a decision was made to select a single or biventricular repair at the second-stage procedure. This point is important, because if we can clearly identify candidates for 2-ventricle palliation, we can modify surgical techniques to promote biventricular potential. Tools at our disposal include anatomic selection criteria (identifying the right patients), manipulation of the size of the atrial septal defect to maintain high enough transmitral flow to promote growth of left ventricular structures, and calibration of the amount of pulmonary blood flow to maximize the potential for left ventricular growth. A study design capable of assessing these tools will require a priori designation of an intended biventricular repair—followed by excellent surgical technique and follow-up as demonstrated by the Giessen group.⁷

Another important new niche for the hybrid strategy is the innovative use of bilateral pulmonary artery banding as an initial staging procedure before the conversion to a traditional Norwood procedure. It is possible that this strategy may have arisen from the common use of bilateral pulmonary artery banding as a “salvage” procedure to stabilize hemodynamically unstable patients, for whom a Norwood procedure is considered to carry prohibitive operative risk. Regardless of the origin of this concept, in this issue of the *Journal*, Davies and coworkers⁸ describe the use of neonatal hybrid management (with or without ductal stenting) as a staging procedure before a Norwood or a comprehensive stage 2 procedure. The conceptual approach is innovative, but proponents of this strategy will need to overcome the burden of proof demonstrating that the interposition of a Norwood procedure between a stage I and stage II procedure is associated with a decrease in overall lifetime morbidity and mortality. Mitigating factors required for this calculus include morbidity and mortality for hybrid stage I procedures, the modified (but not clearly defined) risk profile of Norwood procedures in patients after undergoing “preparatory” hybrid procedures, and the divergent risk profiles of straightforward cavo-

pulmonary shunts (after a Norwood procedure) and hybrid stage II procedures (arch reconstruction and cavopulmonary shunt). With the wide array of variables in play here, comparative outcome studies are likely to require high volumes of patients, and the value of this strategy will not be clear any time in the near future.

This issue of the *Journal* offers multiple perspectives on the hybrid strategy as it marches up the Slope of Enlightenment. Although niches need to be clarified and indications must be refined, it is clear that the hybrid innovation is an important tool in our clinical armamentarium for managing patients with single-ventricle physiology. We simply need to figure out how best to use it.

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