

## Right ventricle to pulmonary artery shunt modification of Norwood procedure: Outcomes, concerns, and controversies

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For neonates with hypoplastic left heart syndrome (HLHS), the Norwood procedure has become the most frequent first-stage management strategy.<sup>[1]</sup> Norwood stage 1 surgical palliation for single ventricle physiology is aimed at providing an unobstructed systemic outflow tract, an unrestrictive intra-atrial communication, a controlled source of pulmonary blood flow, and a reliable source of coronary blood flow. Over the last quarter of a century, improvements in perioperative care and modifications in the surgical technique have all resulted in dramatic improvements in the outcome of the Norwood procedure. One such modification of the Norwood procedure, a right ventricle to pulmonary artery (RV-PA) conduit to supply pulmonary blood flow instead of the modified Blalock-Taussig (mBT) shunt, has been reported by various institutions to contribute to the improved outcome.<sup>[1]</sup>

In the current issue of *Annals* the pooled analysis of non-randomized and retrospective studies of this modification is a welcome addition to the existing literature that validates the beneficial effects of the RV-PA conduit in the short term. The meta-analysis confirms significant reductions in the cardiopulmonary bypass time (standard mean difference, -0.412 minutes, *P* value <0.001) and systolic blood pressure, 24 hours postoperatively (standard mean difference, -0.0689 mmHg, *P*-value = 0.02), and a significant increase in diastolic blood pressure 24 hours postoperatively (standard mean difference, 0.0689 mmHg, *P*-value = 0.01). All these variables have a major positive influence on the immediate postoperative course of patients who are deemed high risk for mortality and morbidity, both in the short as well as in the long term.

This meta-analysis has several strengths, such as, having a clearly focused clinical question, using appropriate inclusion criteria to select primary studies, assessing the quality of selected articles, good reproducibility in the assessment of primary studies, and performing sensitivity analysis, and meta-regression to account for heterogeneity. Nevertheless, it must be mentioned that it has several weaknesses, such as, possibly missing out other relevant studies especially the only randomized

controlled trial (RCT) comparing the two strategies,<sup>[2]</sup> possible selection bias, low quality of primary studies used (due to their retrospective and nonrandomized nature) and lack of data on the length of intensive care unit stay, length of hospital stay, and cost, all important short-term outcomes.

The advantageous effects on early hemodynamics after the Norwood procedure, caused by the introduction of the RV-PA conduit, instead of the mBT shunt, are a direct result of the higher diastolic pressure due to elimination of the diastolic runoff from the systemic and coronary circulation into the pulmonary vascular bed.<sup>[3]</sup> The stable hemodynamics after the first-stage palliation possibly translates into significantly lower mortality and morbidity in the short term. Despite the reported improved early outcomes after RV-PA conduit modification it must, however, be reiterated that serious and valid concerns persist regarding the growth and development of the pulmonary arteries, mid- and long-term ventricular performance, mesenteric ischemia, ventricular arrhythmias, and neo-aortic valve insufficiency.<sup>[1,4]</sup> To these one must add the additional concern, of increased incidence of reinterventions after the RV-PA conduit, raised by the recently published RCT.<sup>[2]</sup>

The concerns and controversies that prevail regarding the RV-PA conduit could partly be attributed to technical redundancy, lack of standardization, and interinstitutional and intrainstitutional practice variations. Furthermore, technical modifications, such as, the use of different materials (ringed Gore-Tex, plain Gore-Tex, homograft conduit), conduit sizes (4, 5, or 6 mm), position in relation to neo-aorta (right or left of the aorta), and anastomosis both, proximally, either with ventricular fixation or epicardial fixation, as well as, distally with a Gore-Tex or biologic patch or direct anastomosis have implications both in the short and long term. Interestingly, neither the recently published RCT nor the large numbers of retrospective studies acknowledge that each of these modifications can act as a confounder in the final analysis. The lack of a standardized surgical technique for RV-PA shunt construction in itself allows for error-generating

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boundaries, and one must not underestimate the role of a variable surgical technique in contributing to an increased rate of reinterventions as suggested by the RCT.<sup>[2]</sup>

Finally, it must be emphasized that due to their undoubted advantages, meta-analyses have an important role in the implementation of evidence-based practice and the shaping of future research, however, meta-analyses are no panacea.<sup>[5]</sup> Caution, therefore, has to be exercised when applying the results of the meta-analyses to clinical practice, due to the methodological limitations of the meta-analyses and limitations of the primary studies used.

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