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REPLY: PATIENT SELECTION IS BOTH THE PROBLEM AND THE SOLUTION

Reply to the Editor:

Shranz and colleagues¹ pull the hybrid stage 1 procedure out from the shadow cast on it by the North American experience, delivering it some light from their experience in Germany. The German outcomes support their approach to use the hybrid stage 1 routinely for the palliation of hypoplastic left heart variants rather than reserving it as a salvage palliation for special-risk patients, as has been the common practice in North America. As with any intervention, patient selection is a strong determinant of outcome, and routine versus salvage indications indeed keep it a problematic, apples-versus-oranges comparison of approaches.

In the North American experience, hybrid stage 1 outcomes are not dissimilar from Norwood stage 1 outcomes, and few centers embrace the hybrid as a standard approach. Despite some encouraging data that suggest the hybrid stage 1 may have a lower rate of renal injury and shorter initial hospital length of stay than the Norwood stage 1 procedure,² interstage mortality was 7% and readmission rate was 75%, with many patients experiencing major adverse events after hybrid repair.³ Further, to properly compare strategies, one must include stage 2, where some early gains of the hybrid may be lost, with longer hospital stay and higher mortality than a post-Norwood stage 2. Prospectively collected data from more than 60 institutions from the National Pediatric Cardiology Quality Improvement Collaborative found the hybrid stage 1 to be an independent risk factor predicting death or transplant, with a 3.45 odds ratio, compared with the Norwood (with Sano conduit).⁴ But that is mostly the experience of hybrid stage 1 applied as salvage, with a lot of high-risk patients in the denominator.

A 15-year experience reported by the group in Germany consisted of 154 patients.⁵ Seven underwent transplant, 7 were relegated to comfort care, and 34 died. Interstage

mortality was 6.7%, and stage 2 mortality was 9%. Notably, 33 patients (21%) in the series were destined for biventricular repair, signaling a patient selection scheme that included a lot of lower-risk patients in the denominator.

Shranz and colleagues¹ make a worthy point that the hybrid approach is benefiting from ongoing refinement, and showing comparable if not improved outcomes where it is applied as the preferred approach. Apart from the discussion of comparability of outcomes, Shranz and colleagues elsewhere cite “minimize[d] surgical stress” incurred by the hybrid approach, particularly with the advent of endoluminal pulmonary artery restrictors that may make a “stress-free” stage 1 palliation.⁶ It is ambitious to call a procedure with a 3-week hospital stay and close to 20% mortality stress-free, although a purely catheter-based approach will no doubt count as a significant refinement, and we look forward to emerging results.

Patient selection bias will continue to muddle comparisons of what appear to be comparable approaches to the early-stage palliation. Evolution of refinements may further improve both approaches. The fact remains that some pre-operative risks will have predestined poor outcomes beyond stage 2, regardless of approach. Although refinements of both approaches are eagerly anticipated, patient selection remains the more relevant filter.

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