turn may finally allow for a prospective study with appropriate stratification by birth weight and other important factors. Then we will doubtless find something else to argue about. In the meanwhile, it is clear that both stagers and primaries have work to do to provide more effective and less morbid treatments for our tiniest patients.

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Commentary: Very nice study...what are we to do with it?

Charles D. Fraser, Jr, MD

Another paper on tetralogy of Fallot (TOF)...really? Cardiologists and surgeons responsible for treating children with TOF are confident and entrenched in their opinions about strategy. We counsel with confidence, almost at times being dismissive about the complexity of TOF. It's a straightforward diagnosis and we know what to do. Or do we?

This is a problematic paper, like a road to nowhere. Qureshi and colleagues¹ expose problems we probably weren't expecting. In babies (<2.5 kg) with symptomatic TOF treated with 2 opposing strategies, initial palliation (surgical or catheter-based) followed by a complete repair or by a primary surgical repair without preceding palliation, results aren't great.

Charles D. Fraser, Jr, MD

CENTRAL MESSAGE

This is yet another tetralogy of Fallot management study... or is it? The question is what are we to do to improve outcomes in this disease?

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Consider:

1. Symptomatic TOF in patients <2.5 kg is worse than most of us would have admitted. Other recent publications have also been sobering in this regard.^{2,3} This study, from leading pediatric heart programs, is concerning—at 5 years of follow-up, whether a child is treated with an initial palliation or a primary repair, their chance of being dead is 15% to 18%. This is not at all how we counsel families.
2. We are all over the map in treatment of TOF, and it is likely that this will get worse before it gets better. The studied cohort of catheter-based therapies for TOF palliation were largely just balloon pulmonary valve

dilations. With the advent and relative acceptance (good or bad?) of ductal stenting, another treatment variable is added, largely not accounted for in this study.

3. The “Perspective statement” is spot on: “A concerted effort from the congenital heart community is needed to address the sobering findings of high mortality...”
4. The “Central Message” is disappointing: “In symptomatic neonates with TOF weighing <2.5 kg, mortality and reintervention was independent of treatment strategy.” This is completely unacceptable. What unintended consequences will result from this nonanswer?
5. How does a “noninferiority” conclusion move the field forward? I can hear that debate at patient management conference...a symptomatic 2.4-kg baby with TOF/pulmonary stenosis—what to do? Dilate the right ventricular outflow tract, stent the ductus, primary complete repair, surgical palliation. Who is right? Everyone? No one?
6. Mortality is tip of the iceberg in this debate. Babies with congenital heart disease have vulnerable brains.⁴ As we debate treatment modalities, we must consider more granular outcomes data. If a cohort of children with symptomatic TOF can be followed with essentially

100% follow-up as in this study, those same patients can undergo neurodevelopment follow-up.

There are solutions to these vexing realities. For one, we cannot accept that there is no optimum strategy. We must respond to the fact that repaired TOF is a chronic disease and results are not nearly as good as we thought. Every single patient must be followed for life, and we must collect more robust data, including neurodevelopmental outcomes, to tease apart the details needed for definitive solutions. For this, the example of this research collaborative, is paramount and the primary hope of specific answers.

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Commentary: Neither “shunt” nor “stent” is a four-letter word

Jonathan M. Chen, MD

For decades, the congenital cardiac pendulum has swung between staunch advocates of either initial palliation or single-stage repair of tetralogy of Fallot (TOF). In parallel,

The sun rises and sets; still the pendulum swings.

CENTRAL MESSAGE

Assessing the ideal contemporary repair strategy for tetralogy of Fallot in newborns may be more complicated than we think.

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despite advances across the continuum of perioperative care, the results of aortopulmonary shunting have reproducibly demonstrated sobering mortality rates with little