the same thing when performing an analysis, a fact missed in KM and CPH methodologies.

We are left wondering whether this type of analysis should become more (or “the”) standard for longitudinal analyses after congenital heart surgery. In the least, it is a valuable tool providing results that could be added to, or compared with, those based on the more typical KM or CPH approaches. We all care most about the long-term outcomes of our patients and are constantly questioning how our decisions and actions during relatively short episodes of care affect them over the life span. This kind of analysis may help us better answer some of the questions that we all

have about complicated patients in whom structural heart disease is often only one of multiple, and competing, risks they continually face.

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Commentary: As good as new: Using modulated renewal to analyze reintervention after truncus arteriosus repair

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As survival for patients with congenital heart disease (CHD) continues to improve, it is important to continuously evaluate our measures of success for these patients. In the current era, the goals of care have expanded beyond simply improving survival. As such, management strategies aimed at optimizing functional performance and overall quality of life should be carefully considered. Such aims are particularly relevant for patients with truncus arteriosus (TA). Although complete repair in early infancy is the established standard of care, with a reported survival rate of 76.8% at 20 years,¹ the morbidity for patients with TA is incurred in the form of multiple reinterventions. Because

Hypothetical repeated reinterventions after truncus arteriosus repair.

CENTRAL MESSAGE

Modulated renewal analysis of truncus arteriosus repair provides strategies to help improve the durability of intervention.

the right-ventricular outflow tract needs to be reconstructed with a right ventricle-to-pulmonary artery (RV-PA) conduit during the initial operation, multiple RV-PA conduit reinterventions are required.² In addition, these children may need truncal valve (TV) reoperations, especially in the setting of abnormal TV morphology.^{1,3,4} For patients with TA, surgical strategies that minimize the frequency and invasiveness of reintervention would improve their quality of life and perhaps improve long-term survival.

As clinicians caring for patients with CHD, we often modify clinical and surgical practices in an effort to provide the most contemporary, evidence-based care. Similarly, it is

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FIGURE 1. Hypothetical freedom from right ventricle-to-pulmonary artery conduit reintervention illustrating a modulated renewal analysis. The *darkest curve* represents the freedom from first conduit replacement after the index operation. Those experiencing a first reintervention are “reset” to time 0. The *second curve* is freedom from second conduit exchange after the first reintervention, and so on. After each reintervention, the likelihood of having another intervention decreases. (Modified from Blackstone and Karamlou.⁶)

necessary to regularly reassess the analytic tools that we use to evaluate outcomes and guide clinical practice. Using an outdated or inappropriate statistical model to study outcomes in CHD is akin to searching for a problem in a new electric vehicle using a diagnostic system designed for a gasoline engine—just because one gets an answer does not mean that it is an accurate one.

In the current issue of the *Journal*, Guariento and colleagues⁵ used their 35-year experience in the surgical management of children with TA to identify risk factors associated with mortality and reintervention after complete TA repair. In addition to excellent long-term follow up and a robust dataset, the authors optimized their analysis using the statistical technique of modulated renewal. In the commonly used Kaplan-Meier method to evaluate survival or freedom from reintervention, each terminating event (ie, death or reoperation) can be accounted for only once. From a statistical standpoint, each patient is limited to analysis of a single end-state.⁶ Clearly this is not a problem when evaluating freedom from mortality, otherwise known as survival analysis. However, if we are interested in evaluating the risk of a patient experiencing multiple, sequential events of a similar nature, an alternative statistical approach must be used.

Unlike the Kaplan-Meier method, where each patient remains under observation for a single event, modulated renewal evaluates the hazard (instantaneous risk) of failure (ie, reintervention) from the most recent intervention rather than from the initial operation.⁷ If we consider a car engine as a hypothetical example, the time from engine production to repair would be considered the first hazard interval. The engine (or patient in our case) is “reset” to time 0, and the risk for failure restarts. Each engine remains under observation for analysis as subsequent events occur (Figure 1). This

allows us to determine how well an engine performs after each rebuild. When observing patients, outcomes provide insight into the success of each interval procedure. In addition, we can identify factors during each interval that if modified, may enhance the durability of an intervention. Given the frequent reinterventions after initial TA repair, modulated renewal is an ideal analytic strategy for evaluating the long-term outcomes after TA repair.

In the present study, TV insufficiency and a smaller RV-PA conduit placed at the initial operation were associated with worse overall survival. The risk for reoperation on the TV was related to the presence of significant TV insufficiency, TV morphology, and TV intervention at the initial operation. Not surprisingly, smaller RV-PA conduit placement at the initial repair was associated with an increased risk of conduit reintervention. Importantly, the data show that a shorter time to reintervention, for either the TV or RV-PA conduit, was a risk for recurrent intervention.

Although the significant findings of this study are somewhat intuitive, the relevant implications should not be overlooked. That is, achieving a durable initial repair is critically important. Optimizing TV function and using a larger RV-PA conduit when possible may mitigate the number of repeat interventions. Moreover, the importance of incorporating an advanced and nuanced statistical strategy should be emphasized. As we continue to seek answers to complex clinical questions, increased exposure to and understanding of a variety of analytic strategies will enhance our understanding and improve the relevance of clinical data. The Boston group should be commended for their excellent outcomes after TA repair. Their dedication to evaluating methods to improve surgical technique will hopefully lead to an improved quality of life for patients with TA.

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