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Commentary: Let's push on medical device innovation

David Kalfa, MD, PhD

Guariento and colleagues¹ from Boston aim to identify independent risk factors for mortality and reintervention after repair of truncus arteriosus using a new, modulated renewal competing risk method, which means, for nonstatisticians, a method that allows researchers to include repeated events into the model while avoiding censoring of information due to early mortality.

The results of this series are not surprising: truncus arteriosus repair still yields nonoptimal outcomes in the current era. The 1-year mortality is 14% with a predicted mortality of 19% at 20 years, the truncal valve (TV) plays a major role in the prognosis of these patients, as we all know. The authors show that a quadricuspid TV, a moderate/severe TV insufficiency or TV stenosis before surgery, and the need for a TV intervention at index repair increase the risk of TV reoperation; TV insufficiency at birth also increases the risk of mortality; and finally, the right ventricle to pulmonary artery (RV-PA) conduit size has a significant influence on the life expectancy and quality of life of these patients as we all know. In this series, smaller conduit size (as a continuous variable) is associated with overall mortality, whereas an RV-PA conduit ≤ 11 mm at index surgery is a risk factor for early conduit reoperation/reintervention. TV and conduit reoperations are frequent: 20% at 10 years and around one-third of patients at 10 years.

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CENTRAL MESSAGE

Truncus arteriosus repair still yields nonoptimal outcomes in the current era. The development of innovative medical devices is the next step to drastically help these patients.

In this series, factors such as low weight, prematurity, extracardiac malformations, coronary artery anomalies, and truncus type A4 were not identified as statistically significant prognostic factors. This lack of statistical significance may be related to the limitations of this study. Besides the limitations inherent to the retrospective nature of this single-center cohort of patients that spans 4 decades, we should note that this series focusing on primary repair of truncus arteriosus does not include the highest-risk patients who undergo bilateral pulmonary artery banding; some confusion bias is not taken into account in the analysis of the role played by small conduits in mortality; there is no granular data on the type and influence of the truncal valve repair; and the body surface area-indexed conduit diameter was not calculated, making the clinical significance of this 11 mm cut-off for the conduit quite unclear.

And now? What do we need to do to improve the quality of life of these patients? Improvement in diagnosis and imaging modalities, intensive care unit management or perfusion technologies may help but will not drastically change the outcomes. What will truly make a difference in the life of our patients is the development of innovative products and medical devices, such as new biomaterials to perform long-lasting valve repair or growing/growth-accommodating valves, tubes or valved tubes that can be implanted in the RV-PA position and the truncal position (because

many of these valves are not and will not be amenable to a long-lasting repair). Some of us are working on it. Time is pressing.

Reference

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Commentary: When complicated statistics may be the best way to answer questions on complicated hearts

Joshua L. Hermesen, MD, Glen E. Levenson, PhD, and Petros V. Anagnostopoulos, MD, MBA

In this issue of the *Journal*, Guariento et al¹ report on a large single-center series of patients with truncus arteriosus treated at Boston Children's Hospital over a 34-year period. The real contributions of this article are not only the relatively unsurprising clinical conclusions regarding the impact of truncal valve insufficiency and original right-sided conduit size on mortality and the risk factors for reintervention, but also the reintroduction to the congenital heart surgical community of the statistical methods used to arrive at those conclusions.

Although surgeon-specific mastery of statistical methods varies considerably, all have some familiarity interpreting the normative Kaplan-Meier (KM) and Cox proportional hazard (CPH) outputs. So what is this "modulated renewal competing risk analysis," and how does it differ from what we are more accustomed to? Technically speaking, it is a modeling approach that allows for multiple types of outcomes and multiple observations/events per patient

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CENTRAL MESSAGE

The statistical methodology used in this single-center study of patients with truncus arteriosus patients should be more widely considered for studying patients with congenital heart disease.

over the course of the follow-up period.² Patients are not censored after the first occurrence of interest, save for mortality, which may be cause-specific. Whereas KM curves are graphical representations of raw data, the curves in this article depict the results from "modeling" survival based on functions and their associated parameters. The reason for the parallel colored lines that may catch one's eye and distinguish them from more familiar KM curves is that there is an underlying exponential function assumed to best represent overall survival, and group differences are estimated using a parameter of that function.

This methodology is not novel in our field but is more commonly used in fields such as oncology, where the question is whether the patient died from their cancer or from some other cause. We commonly ask ourselves similar questions, such as whether the patient died from their cardiac disease or from some comorbid condition or genetic syndrome.³ Our statistician colleagues inform us that accounting for competing risks is generally a more statistically robust and sound methodology that can help account for the fact that death and loss to follow-up may not be

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