Commentary: Regionalization of congenital heart surgery. If you don’t know where you are going, you'll end up someplace else

Bahaaldin Alsoufi, MD,a and Petros V. Anagnostopoulos, MD, MBAb

In the current issue of the Journal, Yoshimura and colleagues1 from Japan analyzed 47,164 congenital heart surgeries (CHS) performed between 2013 and 2018 from the Japan Cardiovascular Surgery Database. They compared observed/expected mortality among 150 programs grouped based on the annual hospital procedural volume: group A (≤50 cases, n = 90), group B (51-100 cases, n = 24), group C (101-150 cases, n = 21), and group D (>150 cases, n = 15). For comparison, they used a Japanese risk model that they termed J-STAT, which is very similar to the STAT model applied in North America. They found that overall mortality following CHS was low in Japan (2.64%). However, they found that observed/expected mortality ratio decreased gradually with increased hospital volume and that it was most significant for J-STAT 3 cases (group A did worse than B, C, D) and J-STAT 4 + 5 cases (groups A, B did worse than C, D). When they examined some index operations such as arterial switch, Rastelli, Norwood, and complex coarctation repair, outcomes were best in group D centers and were especially worse in group A centers. They concluded that group A centers that performed ≤50 cases yearly had worst outcomes in all CHS complexities (likely suggesting that these centers should not exist), and that the largest-volume centers (>150 cases yearly) had the best outcomes, although for complex operations it seemed that programs that performed >100 cases yearly performed as expected.1

This is an important topic, given the ongoing global interest in outcome improvement, with regionalization of care being proposed as an important tool to achieve this goal. The topic of regionalization of CHS continues to generate controversy, given the lack of clear evidence (short of some modeling exercises) of its significance in improving outcomes, and most importantly, the failure of all proposals to assess the full impact of regionalization of CHS on the overall care delivery in the impacted centers (those gaining or losing patients alike), on the education of health care workers, on patients and their families, and on the community overall. There are clear important differences between countries that preclude a cut-and-paste approach to duplicate regionalization experiences. For example, Japan’s geographic area would be smaller than 4 US states (for example, smaller than California) whereas the population of 125 million is at least 3 time more than California (the largest US state by population). Obviously, the amount of travel imposed on families if local centers are closed would be much lower than that in the United States, and the presence of local affordable transportation system makes it less challenging. Moreover, the number of centers in Japan seems very excessive, and the majority of centers are

CENTRAL MESSAGE
Health care, geographic and socioeconomic differences preclude duplication of regionalization experiences. Many considerations should be carefully studied when designing optimal care delivery models.
preforming fewer than 50 cases yearly, and wide variations in hospital resources likely exist between these centers. Finally, there is in general one main congenital cardiac surgeon per center, and the level of training and experience is not as uniform as in the United States. These are all different from the United States, for example, where the number of centers is much smaller, there are more defined qualifications for surgeons who perform CHS, there are very few programs that perform fewer than 100 cases (again, in this study from Japan, programs that performed >100 cases did actually pretty well), and what is considered a large program in Japan (>150 cases) is barely considered a low- to moderate-size program in the United States. All these health and socioeconomic differences limit the ability to extrapolate experiences from Japan or another country to a different country such as the United States.

Outcomes of CHS in the United States can vary among centers. Regionalization of care in larger-volume hospitals has been proposed as a way to improve these outcomes. There are paradigms of successful regionalization in European countries that improved outcomes by concentrating resources in fewer centers of excellence and by closing underperforming units. These countries, like Japan, have a smaller geographic footprint, possess public transport infrastructure, making travel much easier, and do not have the widespread profound socioeconomic differences that can be observed in the United States. In all these paradigms of regionalization, the presence of a National Health System was of paramount importance in making health policy decisions easier to apply and in compliance easier to enforce.

With the exception of the “real-world” paradigms of regionalization in the United Kingdom and Sweden, the majority of literature in support of CHS regionalization is largely based on modeling exercises. There is a fundamental issue with these studies. All these studies are cross-sectional. In these studies, the weak volume outcomes associations documented are used as assumptions in models to predict lives-saved and longitudinal outcomes. However, there is a huge leap of faith to assume that programs that are faced with a large increase in their volume will continue to perform at their current levels of performance. Most hospitals in the United States are run with tight budgets and are aspiring to lean management principles. Allocation of resources, inventory management, and bed and operating room use targets are in some instances so tight that small fluctuations in volume are difficult to manage. The recent staffing crisis that many (most) pediatric hospitals are currently facing has shown how difficult it is to expand the workforce and how challenging is to secure adequate human capital to run operations.

Regionalization of care is not purely an academic decision but a major policy decision that will have profound effects on health care systems and hospitals both that lose and gain volume. To date, these effects of potential regionalization policy decisions have not been adequately examined. It is also worrisome that many previous efforts at regionalization of care in the United States did not significantly change outcomes but have led to access-of-care issues for patients with limited means, minorities, and patients of lower socioeconomic status. In addition, limiting the experience with complicated patients to large centers would affect the level of expertise and comfort of other centers in taking care of these patients. These local centers would likely be the ones assuming care of these patients following discharge from the larger operating centers. Therefore, the impact of regionalization on the care of patients should be assessed longitudinally and not limited to operative outcomes.

Obviously, having a wide variation of outcomes in CHS in the United States, given that 66% of hospitals performing CHS are located within 25 miles of another, would not acceptable. A serious discussion about regionalization should accurately define what the goal of this policy is: if the goal is for most, if not all, hospitals that have CHS program perform as expected, then the study for Japan helps frame the discussion along a much more attainable goal: If hospitals in Japan that do 100 to 150 major cases a year perform as expected across all risk categories, is the logical goal of regionalization the concentration of cases around strategically placed well-performing medium- and large-sized hospitals? If, in contrast, the goal of the regionalization of care is the development of exceptionally performing mega-programs, then how is exceptional care defined? What do we do with large-volume centers that are not performing exceptionally? Who makes this decision, how will this decision be enforced, and how can we make sure that the acute increase in volume will not result in a deterioration of services and outcomes in hospitals that gain and lose case volume?

At any rate, regionalization is a major policy decision. We all have a vested interest in getting this decision right. However, one has to admit that medical economists, sociologists, hospital administrators, and even politicians are equally important in this debate and experienced in conducting thorough assessments of the risks and benefits of major policy decisions. We all have to work together to ensure not only optimal outcomes of cardiac patients, but the best possible outcomes for all patients, families, hospitals, and health systems and the American public in general.

References


