Leaving Neverland
A Randomized Trial for Coarctation Shows Pediatric Interventional Cardiology Is Growing Up

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Coarctation of the aorta is commonly considered a relatively simple form of congenital heart disease. On the basis of early knowledge of the significant mortality associated with unrepaired coarctation, surgical therapy was first developed and performed in the mid-1940s. In many ways, the seemingly simple problem of pediatric coarctation has lent itself to a myriad of treatment strategies, including transcatheter intervention. The community of pediatric cardiologists and cardiac surgeons, faced with these broad options, has failed to reach consensus about optimal management. Even 12 years after publishing the early results of a randomized trial comparing angioplasty with surgery in the treatment of children with coarctation, Cowley and colleagues continue to acknowledge the ongoing and active controversy surrounding the topic.

In this issue of *Circulation*, Cowley and colleagues present the long-term results of this trial, with a relatively small number of patients and incomplete follow-up. Using a composite outcome that comprises reinterventions and aneurysm formation, the authors draw the tentative conclusion that surgery may provide better long-term outcomes than does balloon angioplasty. This conclusion can be challenged on a number of fronts. For example, the need for 2 catheterizations may not necessarily be considered a poorer outcome than a single thoracotomy. Furthermore, as with all long-term outcomes in developing fields, the results reflect only those of older practices. Increased experience with angioplasty techniques and the use of aortic stents have likely altered both short- and long-term results of angioplasty for coarctation. Similarly, as the authors note, surgical approaches to coarctation have changed over time.

Reservations about angioplasty have always centered around the incidence of aneurysm formation, an anticipated complication after the experimental finding that successful angioplasty imparts a tear in the intimal and medial layers of the vessel wall. In mid- and long-term follow-up, rates of aneurysm formation have varied widely; this variability has been attributed to differences in catheter technique and inconsistent definitions of aneurysm. In the study by Cowley et al, despite the finding of a higher incidence of aneurysm in the angioplasty group, the data remain far from compelling in favor of primary surgical therapy. As in previous reports, uncertainty about the clinical significance of aneurysm in the late postangioplasty setting is reflected in the management of these lesions once diagnosed (only 2 of 7 patients were referred for surgery).

Despite these shortcomings, the article by Cowley and associates is an extremely important one in our field: It represents the first prospective randomized trial in pediatric interventional cardiology with an intermediate- or long-term outcome. As such, it flies in the face of the prevalent view among many in the field that randomized study design and prospective data collection are fraught with prohibitive difficulties. Although randomized controlled trials in pediatric interventional cardiology are often unnecessary and may be difficult, they are not impossible. Perhaps more important, they represent a vital maturational stage in any field. For >2 decades, our institution and others have been unwilling to pursue prospective multicenter randomized trials in interventional pediatric cardiology for a number of reasons: (1) Highly variable operator skills in a brand new field threatened to confound results, (2) optimum therapeutic plans were still in development, and (3) patient selection criteria were only beginning to emerge for some newer techniques. These objections are losing validity in the current era. Operator skill is becoming more uniform, inherent technical variability has been reduced, and patient selection is better understood. Standard therapeutic plans now include operations with low operative mortality and excellent results. As the field of pediatric interventional cardiology progresses to maturity, the need for analysis of results and keen-eyed self-criticism is becoming imperative.

The reluctance of the congenital heart disease interventional community to embrace randomized prospective trials is only one side of the fundamental immaturity of this field. The prevailing ways in which we communicate information remain primitive. Positive single case reports abound, and serious or fatal adverse events remain unreported. Presentations at major scientific meetings have poor scientific rigor or involve patient testimonials, and strong financial ties to commercial products result in meetings that purport to be academic but are inherently biased—presented by self-appointed, self-perpetuating review panels. About 21 years ago, the pediatric community first realized catheter closure of an atrial septal defect, device occlusion of patent ductus arteriosus, and dilation of aortic and mitral
valves in children. The age of majority is upon us, and it seems time for the field of interventional cardiology in congenital heart disease to grow up. The article by Cowley et al is one important step in that necessary and inevitable process.

References

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