

EDITORIAL COMMENT

What Is the IMPACT of Practice Variation in Congenital Interventional Cardiology?*



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One of the greatest challenges facing outcomes research in the field of pediatric and congenital interventional cardiology is the relatively uncommon nature of the conditions we treat. As a result, studies with very large numbers of patients are generally lacking. Single- or multicenter retrospective studies with limited numbers of patients are often the best evidence available on which to base clinical decisions encountered every day. This challenge is never more apparent than when our field attempts to establish practice guidelines for congenital interventional catheterization procedures for which procedural volumes are comparatively small and patient size and anatomic characteristics of interest can be so diverse. Such is the dilemma confronting congenital interventional cardiologists when faced with decision making in the transcatheter treatment of congenital aortic and pulmonary valvular stenosis. Significant clinical differences exist between subsets of patients such as age and size, anatomic features of the valves and presence of important comorbidities that affect outcomes. In an effort to overcome these limitations, informal registries were created to help define acute results and short-term outcomes for these interventions (1,2). These and other reports helped establish the role of balloon valvuloplasty as the standard of care treatment for congenital valvular aortic and pulmonary stenosis, accepting the same appropriateness criteria developed by expert consensus for surgical treatment in an earlier era. More on that later.

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To gain further insight and understanding of role for and outcomes of transcatheter congenital cardiovascular interventions, the IMPACT Registry, part of the National Cardiovascular Data Registry, was established by the American College of Cardiology Foundation in 2011 (3). Prospective, standardized, and pre-specified demographic, clinical, procedural, and institutional data are collected and entered voluntarily by participating centers. Rigorous monitoring and quality assurance standards are applied to ensure the integrity of the data collected. In its current form, the IMPACT Registry collects only acute procedural data, an important limitation when these data are applied to outcomes research, in which the longer term benefits or risks of intervention are not available. Of course, all outcomes research requires a benchmark upon which to judge the results of interest. At times in our field, that benchmark is published guidelines often based on expert opinion. More about that later as well.

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In this issue of *JACC: Cardiovascular Interventions*, Glatz et al. (4) report their analysis of practice variation in the performance of balloon aortic valvuloplasty (BAV) and balloon pulmonary valvuloplasty (BPV) reported to the IMPACT Registry between January 1, 2011, and September 30, 2015, encompassing 1,071 BAV and 2,207 BPV procedures (4). The indication for intervention in the vast majority was "high resting gradient" with the reported peak-to-peak catheter gradient at intervention compared with guideline recommendations for treatment (5). The catheter-derived gradient at intervention was then dichotomized as falling above or below guideline recommendations. Procedures in which the pre-treatment gradient fell below the guidelines-specified value were deemed at variance with those guidelines. Multivariate analysis and various statistical models were created to measure and assess practice variation against hospital characteristics. The

result was measurable hospital-level variation in practice for both procedures. For BAV, differences across census regions were identified, with hospitals in the East and South more likely to perform interventions consistent with published guidelines compared with those in the Midwest and West. For BPV, regional differences in practice variation were not identified. However, interhospital variation was found to be significant. The investigators are to be congratulated for using the IMPACT Registry in a new way as a quality assessment tool to address potential quality gaps for BAV and BPV by assessing practice variation with published standards. They point out, quite correctly, that it is tempting to speculate on the possible reasons for these practice variations. That these variations exist is beyond dispute. Whether the variations identified constitute evidence of gaps in quality of care is another thing. The investigators rightly note that the current acute procedural data collected in IMPACT do not permit an assessment of actual outcomes or resource utilization for these interventions in particular. Longitudinal follow-up of patient outcomes in these cohorts is required to accurately make the connection between practice variation and quality of care.

In the meantime, an important question also posed by this study design is the validity of published practice guidelines as the quality comparator for these procedures and their applicability to current congenital interventional practice. A close examination of the evidence used to establish treatment guidelines for balloon valvuloplasty intervention in both congenital aortic and pulmonary valve stenosis reveals that the threshold for treatment is based largely upon surgical outcomes defined more than 40 years ago (6,7). No specific studies have ever been performed to define a threshold for intervention on the basis of outcomes for either BAV or BPV. Instead, criteria established largely in the surgical era have been applied to percutaneous interventions. Single- and multicenter retrospective studies for BAV

and BPV codified these treatment thresholds by consistently demonstrating improved safety profiles and largely equivalent effectiveness compared with historical surgical outcomes. From there, the field was off to the races, not ever looking back to ask an important question: Are these gradient thresholds for treatment established in the surgical treatment era decades ago the appropriate yardstick with which to inform treatment guidelines in the current less invasive percutaneous treatment era? Furthermore, are these thresholds for treatment of sufficient validity to judge quality of care? Unless and until prospective, longitudinal follow-up of percutaneously treated and untreated patients with congenital aortic and pulmonary valve stenosis is available, we may not be able to adequately assess whether intervention at relatively lower gradients does, in fact, represent a more aggressive pattern of practice that exposes patients to additional risks or expense.

It is precisely this dilemma that the IMPACT Registry may help us solve. The numbers of patients undergoing BAV and BPV treatments far exceed any prior population studies published. The ability to define thresholds for intervention will require longitudinal follow-up of both treated and untreated patients. This may be a tall order but is a worthy undertaking. To be able to use a new and improved IMPACT to define best practices on the basis of high-quality outcomes research will require a considerable investment of time and energy. However, the value to our patients will be worth it. Using contemporary, organic, real-world outcomes to drive care guidelines rather than stale, expert opinion based on decades-old data from another era is a reality within our grasp. The important work of Glatz et al. (4) is good start.

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