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Commentary

Time for a Change, in Culture Too!

Michael C. Slack *

Department of Pediatrics, University of Maryland School of Medicine, Baltimore, MD, United States of America
Congenital Cardiac Catheterization Laboratory, University of Maryland Medical Center, Baltimore, MD, United States of America

In this issue of CRM a limited comparison of treatment outcomes between surgical and percutaneous pulmonary valve replacement in patients with right ventricular outflow tract "dysfunction" is presented [1]. Interestingly, the authors mined their data using a *retrospective* approach from something called the Nationwide Readmission Database-2014 using specific ICD-9 codes from which to derive comparison data. Also of note, the data utilized in this retrospective analysis covers a period of time only through 2014. Since this time, pulmonary valve replacement practice strategies have been evolving rapidly. The authors are to be commended for their efforts, in the absence of any prospective data, to provide at least some information comparing how patient fare using percutaneous vs. surgical approaches. One must recognize that there are significant limitations commonly encountered when administrative (billing/coding) databases are mined retrospectively for clinically relevant comparisons.

Unfortunately, the extent of limitations resulting from the use of the NRD database may exceed the reliability of some of the conclusions promulgated. First, the comparison groups (PPVR vs SPVR) are quite disparate in size with the percutaneous pulmonary valve replacement patients only representing 18% of the total group. Also the definitions of the types of underlying anatomic subsets as well as the precise types of "RVOT dysfunction" are not well delineated due to the NRD-2014 use of non-specific generalized ICD-9 diagnostic codes well known to lump many clinically important discriminators into a single numbered group. It is well known in the clinical setting that there are at least three major groups of patients in whom pulmonary valve replacements are considered. These include, right ventricular to pulmonary artery conduits, previous surgical pulmonary valve replacement (almost exclusively bio-prosthetic surgical valves) and native outflow tracts either previously surgically altered or unaltered. The NRD-2014 database clearly cannot accurately discriminate between these groups and allow for meaningful treatment strategy comparisons. Additionally, the comparison presented does not account for important trends in clinical practice which were occurring in the time period between 2012 and now. Many, if not most, centers were rapidly migrating away from implanting the Melody Valve to the use of the Sapien XT and more recently to the Sapien 3 Transcatheter Heart Valves (THV). Additionally, the field was migrating from treating primarily RV to PA conduits to also addressing the larger diameter native outflow tract groups percutaneously with or without the concomitant use of large diameter "foundation" stents. The impact of these rapidly moving changes in percutaneous clinical practice are not represented in the NRD-2014 and may make this comparison somewhat inaccurate if not a bit outdated.

Despite these significant limitations, it is interesting to note that percutaneous pulmonary valve implantation demonstrated a trend for improved outcomes with respect to shorter length of hospital stay, lower risk of bleeding (as defined by need for blood transfusion), and lower overall hospital costs. Clearly, mortality as a discriminator did not separate the surgical and percutaneous approaches as rates for both groups were very low. With respect to reported rates of infective endocarditis (I.E.) referenced in this paper (1.7 for PPVR vs. 3.1 SPVR), these may be somewhat misleading. For the PPVR group, the reported rates vary dramatically with respect to the type of percutaneous valve being implanted (Melody vs. Sapen). These differing rates (likely more accurately a composite of 9–10% for the percutaneous group) have been a major driver with respect to the evolution of percutaneous pulmonary valve implant practice. The markedly high rates of I.E. have clearly driven many implanters away from the Melody Valve towards the routine use of the Sapien 3 THV even despite its lack of specific FDA indicated approval for the pulmonary position. Clearly there are still size limitations even with the largest S3 THV since, particularly the native and surgically transannularly patched right ventricular outflow tract (RVOT), frequently tends to be just beyond the range of even an over-expanded 29 mm S3 THV. The Melody Valve was the first human heart valve to be replaced percutaneously in September 2000 at Hospital Necker in France [2]. Despite this head start in the effort to provide percutaneous valve replacement alternatives, no further improvements in the Melody Valve became available during the subsequent 19 years! Over the more recent several years there has been ongoing work, albeit painfully slow, on a valve optimized for the native RVOT. Despite the native RVOT representing the largest potential patient group in whom a pulmonary valve revision is clinically needed, progress continues to be slow. Sadly, the typical product development timeline that has provided two to three new TAVR valve iterations from several manufactures, has not resulted in any new percutaneous pulmonary valve approvals. Much of this may be explained by market drivers and industry resource allocation, but what remains is that we still don't have a percutaneous pulmonary valve for the native RVOT. There may be some light at the end of this tunnel with the current on-going Trial of the Edwards Alterra

* 110 S. Paca Street, Children's Heart Program, 7th Floor, Baltimore, MD 21202, United States of America.
E-mail address: mslack@som.umaryland.edu.

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Adaptive Present which can be combined with a Sapien 3 THV to treat the native RVOT [3]. This self-expanding nitinol hour-glass shaped stent-like platform allows downsize adaptation of oversized RVOTs to create a secure "foundation" into which a large Sapien 3 THV, which would not otherwise be stable, can be securely implanted. In addition, uncovered stent cells in the distal portion provide for flow preservation into the branch pulmonary arteries. This new technology promises to overcoming several limitations currently encountered in the attempting to percutaneously re-valve large patulous RVOTs using off the shelf large diameter uniformly cylindrical stents combined with the S3 THV. Another promising valve trial is the Pulsta Valve Trial (https://www.clinicaltrials.gov. NCT02555319) [4] which utilizes an hourglass shaped self-expanding stent combined with an integral treated porcine pericardial leaflet valve attached inside the stent. Results remain to be seen and there are some concerns regarding size limitations of this valve relative to the wide range of RVOT dimensions encountered in clinical practice.

Once dedicated purpose-built percutaneous pulmonary valve implantation platforms for the RVOT have become available and sufficient experience derived, then we will likely be able to make meaningful and accurate outcome comparisons between PPVR and SPVR using prospective randomized controlled trial designs. Still, there is one major hurdle that will remain. The long held "cultural" practice in the field of congenital heart surgery which has historically avoided direct prospective randomized controlled trial comparisons between percutaneous treatments and surgery is long overdue for abandonment. Such trials in the adult structural cardiovascular space have provided very useful (and some might say frequently surprising) information on which to base sound clinical practices with respect to patient selection and type of treatment [5,6]. It is critically important that these types of prospective randomized comparison trials be done in congenital heart disease as well. Only once this avoidance era is left behind forever by embracing long overdue direct prospective randomized clinical trial comparisons of percutaneous interventional treatment to surgery in congenital heart disease, will we have reliable data on which to base best practices for pulmonary valve replacement therapies. When this happens is yet to be determined, but one thing is for certain, it will be a welcome and refreshing change for all.

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