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EDITORIAL COMMENT

The Edwards SAPIEN Valve in the Pulmonic Position

The Not-So-New Kid on the Block*

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Right ventricular outflow tract (RVOT) dysfunction manifesting as stenosis, regurgitation, or a combination of both, is one of the most common late morbidities after cardiac surgery that a congenital cardiologist must manage. Timing of repeat surgical treatment of the dysfunctional RVOT is balanced with the knowledge that any valve placed in this position again faces the likely prospect of failure and the need for recurrent open-heart surgeries. In 2000, when Bonhoeffer et al. (1) described the first ever successful transcatheter valve implantation with what ultimately became the Melody transcatheter heart valve (Medtronic, Minneapolis, Minnesota), the paradigm shifted. Since that landmark achievement, the Melody valve has been implanted in more than 13,000 patients worldwide, with numerous reports documenting excellent early and midterm outcomes (2). Although this valve has profoundly changed how we manage patients with RVOT dysfunction, like any device, it has its limitations. Frame fracture, endocarditis, and a maximum implantation size of 22 mm are all viewed as possible limitations of the Melody valve.

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In this issue of *JACC: Cardiovascular Interventions*, Plessis et al. (3) report the results of a French multicenter registry designed to prospectively examine the procedural success and short-term effectiveness of the Edwards SAPIEN valve (Edwards Lifesciences, Irvine, California) placed in the pulmonic position in patients with dysfunctional RVOT. The authors are to be congratulated on collaborating for the purpose of reporting results from an entire country on this important device. Although designed initially for the aortic position, the SAPIEN valves have been used with increasing frequency in the RVOT for treatment of both conduit and "native" or patched RVOT dysfunction (4). In the current study, transcatheter pulmonary valve implantation (TPVI) was attempted in 71 patients, all meeting current, standard criteria for pulmonary valve replacement with a median age of 26.8 years. The majority were minimally symptomatic (59% in New York Heart Association functional class I or II) and had previously undergone at least 2 cardiac surgeries (81.7%). Importantly, nearly a quarter of patients (22.5%) had native or noncircular patched RVOT, all of whom underwent successful valve implantation. Historically, this has been a challenging population for TPVI because the large size of these RVOTs often precludes treatment with a simple Melody valve implantation (5). This study further supports the notion that the availability of larger diameter valves (26 and 29 mm) will further expand who can be treated with TPVI. The importance of this cannot be overstated because it is estimated that 75% to 85% of patients currently in need of pulmonary valve placement fall into the native RVOT category. Implantation success rate overall was 95.8%, and nearly all underwent placement of a pre-stent. This high implantation success rate is consistent with other recent studies and suggests that whereas the current SAPIEN delivery systems were not designed for use within the right heart, the valve can almost always be delivered successfully to the RVOT. That being said, for the SAPIEN to

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become a mainstay in the congenital interventional catheterization armamentarium, delivery system improvements must be made to facilitate safe and simple passage through the right heart. In the current series, all 3 patients who did not receive a valve may have benefitted from a delivery system better suited to the right heart. Additionally, although not noted in this series, there have been reports of tricuspid valve damage as a result of manipulating this stiff delivery system with its uncovered valve through the right heart (6).

Including the aforementioned complications, a total of 4 major procedural complications were reported for this series, including 1 death related to pulmonary artery guidewire perforation and 1 near-death as a result of a left anterior descending coronary artery compression, successfully treated with percutaneous revascularization. Although both of these complications have previously been reported with TPVI and neither is specific to the SAPIEN valve itself, they serve to remind us of the inherent hazards associated with these procedures and support the contention that only operators who routinely perform interventions within the right heart (e.g., RVOT and pulmonary artery stenting), and have extensive knowledge of congenital heart disease should be performing TPVI. As noted by the authors (3), all major adverse events occurred within the first 15 patients, suggesting a learning curve, as well as perhaps the superiority of the more recently available SAPIEN S3/Commander compared with the older SAPIEN XT/NovaFlex for use in TPVI.

As mentioned in the preceding text, the practice of pre-stenting, placing 1 or more bare-metal stents in the RVOT, has become standard practice during TPVI. The initial rationale behind this was to build a protected "landing zone" for the Melody valve, which is prone to fracture when exposed to the hostile confines of the RVOT (e.g., heavy calcification, severe stenosis, compressive and rotational forces). Placing 1 or more bare-metal stents within the RVOT significantly reduces the incidence of Melody fracture, thereby greatly reducing a leading cause of TPVI failure (7). The same rationale cannot and should not be used for the SAPIEN valve. With more than 100,000 implantations, primarily in the aorta, but including >2,300 pulmonic implantations, I know of no reports of frame fracture with this device. As experience with SAPIEN TPVI has grown and the longer S3 valve has become available, several centers have begun to abandon routine pre-stenting before SAPIEN TPVI. There are several potential advantages to this approach, including shorter fluoroscopy and procedure times, easier valve delivery, and a simpler, more efficient procedure, making this an important topic warranting further study.

In terms of valve performance, this series confirms excellent immediate hemodynamic results observed in other studies following SAPIEN TPVI, including treatment of native or patched RVOT. Unfortunately, midterm follow-up data reported in this series were limited. Details regarding gradient reduction and absence of pulmonary regurgitation at 1 month were encouraging but were not reported in the 92% of patients with 1-year follow-up data. There is mention of 1 late death, 11 months after implantation related to heart failure, and the need for 3 surgical interventions. Two of these were prompted by transcatheter pulmonary valve dysfunction, 1 with endocarditis and 1 with "bioprosthesis dysfunction." Although no further details are provided, these registry data confirm, as does the U.S. COMPASSION trial (COngenital Multicenter Trial of Pulmonic VAlve Regurgitation Studying the SAPIEN InterventIONal THV) (personal communication, D. Kenny, May 2018). that endocarditis does occur following SAPIEN TPVI even with limited early follow-up. Because the incidence of endocarditis is a time-dependent variable, it is premature to conclude, as some authors have done in the past, that the incidence of endocarditis is lower with SAPIEN TPVI than Melody TPVI. Clearly, there is a need for more data and longer follow-up with SAPIEN TPVI before any conclusions regarding superiority or inferiority when compared with Melody TPVI can be accurately made. What is clear from this and several other recent reports is that the larger-diameter SAPIEN valve with its long track record within the aortic position, fracture resistant frame, and promising early TPVI results will play an important role in the treatment of congenital heart patients with RVOT disease. This is particularly true for those previously untreatable patients with larger patched or native outflow tracts, making the SAPIEN valve a welcome addition to the congenital interventional cardiologist's arsenal. Thus, I think it is high time for us to welcome the not-so-new kid on the block to the congenital side of the street.

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