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EDITORIAL COMMENT

Paravalvular Leak Closure

Time to Standardize Clinical Endpoints?*

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Aortic paravalvular leaks (PVLs) result from an incomplete seal between the sewing ring of a prosthesis and the native annulus. This is often related to annular calcification, infection, suturing technique, and type of prosthetic valve (1,2). Symptomatic PVLs are known to increase morbidity and mortality among patients with surgically implanted prosthetic aortic valves. Although the majority of patients with PVLs remain asymptomatic, about 1% to 5% present either with symptoms of congestive heart failure due to volume overload and/or hemolytic anemia caused by sheer stress on red blood cells when passing through the defect (3). Despite high technical success rates in percutaneous closure of PVLs reported in multiple small series (4,5), there is a paucity of data on both acute and long-term outcomes in this group of patients. Alkhouli et al. (6) should be commended for their experience in the treatment of aortic PVLs. This is the largest published series on the percutaneous treatment of aortic PVLs.

Frequently, PVL lesions are not circular but rather crescent shaped, with long serpiginous tracks. Successful crossing and closure of these leaks is often challenging and time consuming. Alkhouli et al. (6) describe their experience with the use of various Amplatzer Vascular Plug (AVP) devices (St. Jude Medical, St. Paul, Minnesota) in the treatment of aortic PVL closures over a period of 9 years. Currently, the AVP II is the most commonly used device in the United States. However, despite their popularity, the use of AVP II carries a risk for device overhanging, which in turn can lead to obstruction of coronary ostia, interference with valvular flow, or prosthetic dysfunction, especially that of mechanical valves. The oblong shape of the AVP III device may be better suited for closure of some crescentic PVL lesions, but this device is currently not available in United States. "One size fits all" may not be the best approach to close PVL lesions. Our choice has evolved over the years to the use of multiple small devices rather than a single large device, as the radial strength of the latter may lead to further dehiscence and extension of the PVL.

The success rate of these procedures is dependent not only on operator skills but also on the reliability and quality of advanced imaging modalities. The new fusion imaging technology of real-time 3D Doppler echocardiographic images with real-time fluoroscopy may facilitate procedural success and better assessment of the result. When it comes to the choice of percutaneous approach, the type of the valve involved, location of the leak, and presence of calcification will help determine the best access. In their paper, Alkhouli et al. (6) describe in detail the different approaches and techniques for percutaneous treatment of aortic PVL. Although retrograde closure of aortic PVL is most commonly used, alternative approaches such as antegrade transseptal or percutaneous transapical access with or without exteriorizing rail may be needed for some cases, as described by the investigators.

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As reported by Alkhouli et al. (6) in this issue of *JACC: Cardiovascular Interventions*, technical success, defined as mild or less residual PVL, was achieved in 62% of the attempted procedures, with a 7.6% rate of in-hospital major adverse cardiac events rate. At 30 days, the rate of major adverse cardiac events was reduced to 5.1%, and transfusion requirement was eliminated in 88% of the patients. There was not only significant improvement in New York Heart Association (NYHA) functional class among patients with

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mild or less residual PVLs compared with those with greater than mild residual PVLs but also better long-term freedom from repeat cardiac surgery. These findings are consistent with previously reported experience from the same institution (5), in which the overall success rate was 77% for closure of 141 defects (78% mitral and 22% aortic). In a recent Bayesian meta-analysis of 362 patients (7), using cardiac mortality as a primary endpoint, successful percutaneous PVL closure translated into lower cardiac mortality, superior NYHA functional class, and less need for repeat operations. The apparent disparity between the "technical" and "procedural" success rates is related largely to the underlying pathology associated with PVL and the limitations of current device technology. Among other factors, history of infective endocarditis is a strong predictor of high recurrence rate, as reported by Alkhouli et al. (6). In 1 series, macroscopic evidence of infection was seen in 67% of patients undergoing reoperation for aortic PVLs, despite negative blood cultures (8). Operator and institutional experience also plays a major role in the success rate of PVL closure. However, lack of standardization of definition of clinical endpoints makes it difficult to assess and compare these results.

The current indications for percutaneous PVL repair described in the valvular heart disease guidelines of the American College of Cardiology and the American Heart Association include patients with prosthetic valves and symptomatic heart failure (NYHA functional classes III and IV) and persistent hemolytic anemia, who have anatomic features that are suitable for percutaneous surgery at centers of expertise (9). In addition, the current American College of Cardiology and American Heart Association guidelines on the management of valvular heart disease recommend routine surveillance transthoracic echocardiography at 3 years after valve surgery (10). We believe that after the initial baseline post-operative evaluation, yearly follow-up is necessary to better characterize the true prevalence of PVL. After PVL closure, yearly follow-up assessment is also indicated to determine continued safety and efficacy.

We have indeed come a long way since we first started closing PVLs percutaneously more than 3 decades ago (11). Our experience has not only helped us develop better understanding of the characteristics of PVLs but also anticipate complications associated with treating these lesions. We are still in the early stages of technological advancement of devices that can be used in PVL closure. In our opinion, the choice of appropriate device along with pre-procedural planning using advanced imaging modalities is critical in improving procedural success rate and in reducing the rate of periprocedural major adverse cardiac events. The lack of standardization for selecting appropriate clinical endpoints in reporting of transcatheter PVL closure for sutured surgical valve poses a major problem. The upcoming consensus document from the Paravalvular Leak Academic Research Consortium will provide more standardized definitions that will enhance the ability of future studies to define clear endpoints and conclusions.

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