Plugging Paravalvular Leaks After Transcatheter Aortic Valve Replacement
Why and How?*
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Paravalvular leaks or paravalvular regurgitation (PVR) occur after most transcatheter aortic valve replacements (TAVRs) utilizing the first- and second-generation devices. They are generally mild and are seemingly of no clinical significance, although controversy exists on this point (1,2). When PVR is moderate or greater, it is clinically significant, blunting clinical improvement and left ventricular chamber remodeling, and the optimal management has not been defined (3,4). The emphasis has been on preventing PVR by better sizing and placement of the valve (3).

Is significant PVR a common issue for TAVR centers? Even a low estimate of 5% of patients having moderate to severe PVR would yield 1,250 cases in the United States initial experience, with the current number of patients receiving TAVR entered in the Society of Thoracic Surgeons/American College of Cardiology TVT (Transcatheter Valve Therapy) Registry exceeding 25,000. A recent meta-analysis of 12,926 patients showed a pooled estimate of 11.7% with moderate to severe PVR post-TAVR (5). It thus seems odd that there are so few reports of attempts to treat these patients by PVR closure.

Does the burden of aortic regurgitation from a paravalvular mechanism carry the same risk proportionate to severity as all other forms of TAVR-AI (i.e., TAVR-associated aortic insufficiency that is central rather than paravalvular)? Presently, we do not have enough data to answer this question, in part because central aortic regurgitation following TAVR is uncommon.

With that background, in this issue of JACC: Cardiovascular Interventions, we have a publication from a multicenter experience on performing transcatheter plugging of PVR (6). Previous reports have been useful in defining potential technical approaches (7,8). The current publication from 4 experienced TAVR centers has a total of 24 patients. It is unclear what the denominator is of the total TAVR volume, but 24 patients represent a small fraction. They demonstrate procedure success in 88.9%, but the long-term mortality remains high and consists of significant noncardiac causes in many.

An important and useful aspect of this paper is its description of the process of determining the cause for the PVR. There is a variety of causes, and some, when identified at the time of the index TAVR, may result in immediate action such as valve-in-valve. Therefore, it is important to understand that the patients reported here are those who had the index TAVR completed, often remotely, and subsequently had come to clinical attention. They all had symptoms in the setting of a demonstrated PVR that was at least moderate. Patient selection and technical details were decided by the center, and no standardized approach was used. Likewise, there are challenges in quantifying PVR and then linking the PVR to the symptoms of these complex patients post-TAVR who often have other reasons to have symptoms and a reduced functional state (4).

The finding that mortality remained high despite PVR closure is surprising, because the therapeutic intervention of closing PVR was usually successful and the Society of Thoracic Surgeons score was only
moderately elevated. This, too, points to the fact that these were highly-selected patients. In the absence of a control group, it is impossible to make conclusions about the effect of PVR closure on outcomes. It would appear to be the correct management, when carried out in centers experienced with PVR closure, but this study needs to be classified as observational, thought provoking, and hypothesis generating.

Fortunately, as pointed out by the authors, the prevalence of PVR is expected to soon significantly drop as third-generation devices enter clinical practice. These devices and delivery systems have cuffs to better seal the annular region and can be repositioned. The rapidly-evolving TAVR technology thus makes it difficult to organize and conduct a prospective study with a control group in a timely fashion.

The area of PVR closure has evaded industry-sponsored device trials due to the small market and the perception of major regulatory hurdles. The TVT Registry captures reintervention after TAVR, but it is unclear how many centers classify PVR closure as reintervention, and granular data are not gathered to better understand the outcomes of PVR closure. It is likely that the effect of more than trivial PVR on 1-year TAVR outcomes may be better understood with registry data, although the lack of standardized approaches to quantification of PVR will be a problem.

The treatment of PVR following TAVR is important to put in the context of the growing use of transcatheter therapies for all types of PVR. The last 5 years have been significant in improving our ability to successfully treat PVR including the following:

1. The availability of new closure devices, particularly vascular plugs, that are used “off-label;”
2. The ability to use smaller delivery catheters and special wires needed to cross the lesion, advance the delivery catheter, and deliver a plug;
3. The increasing sophistication of image guidance, particularly 3-dimensional transesophageal echocardiography registered with fluoroscopy; and
4. The growing experience of select centers in performing PVR closure.

PVR closure following TAVR is quite different than PVR closure for surgically-implanted valves. The stent that is part of TAVR makes PVR harder to visualize, quantify, and cross with equipment. The size and shape of PVR following TAVR is difficult to characterize by CTA, angiography, and transesophageal echocardiography due to the imaging artifacts and blind spots produced by the cage. In addition, the heavily-calciﬁed valve remains and further affects imaging, the creation of a complex PVR shape, and the challenging technical issues of crossing and delivering a plug. Therefore, in general, PVR closure following TAVR is often more difﬁcult than PVR closure following surgical AVR.

Centers that are considering performing PVR closure need to make a major commitment to the time needed, special inventory, the learning curve, and the team needed to perform this unique structural heart intervention. Of the approximately 350 TAVR centers in the United States, it is unknown what percent are performing PVL closure and their results.

In selecting patients for PVR closure after TAVR, what are reasonable indications? First, there must be an unremitting clinical problem, such as persistent symptoms, left ventricular chamber dilation, or recurrent heart failure. Clinically-important hemolysis is rare in the setting of TAVR. Second, there must be evidence of at least a moderate degree of PVR. Third, the leaks must be technically approachable. Finally, the benefit and risk balance must be clearly articulated and individualized for the patient and family. This paper would suggest that experienced centers have a relatively high threshold for offering PVR closure.

This important report by Saia et al. (6) shows that this procedure can be time consuming, is not predictable in its outcome, can have major complications, and may not clearly provide the major improvement in prognosis that might be expected. We should be appreciative of these authors for making the effort to combine their experience so we might all learn from them. We need reports from more than only 24 patients to better understand the optimal management of this vexing clinical problem for all TAVR programs.

REFERENCES


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