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Have We Found the Ideal Plug for Post-TAVR Paravalvular Leaks?

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Patients with paravalvular leaks (PVL) following transcatheter aortic valve replacement (TAVR) seem to have worse outcomes, even if the regurgitation is mild and does not manifest major hemodynamic consequences [1]. While it is debated whether PVL are a cause for worse outcomes or merely markers for significant patient comorbidity, there are nevertheless a small number of patients who manifest significant medically refractory heart failure due to severe regurgitation from PVL.

Treatment of PVL is complicated. Vascular plugs have been used to treat surgically implanted bioprosthetic and mechanical valve PVL in patients with varying success [2]. The currently available vascular closure devices available in the US market are not always well fitted to the irregular, crescent shape of the PVL, which can lead to hemolysis, device embolization, interference with prosthetic leaflets, or coronary occlusions. In addition to the crescentic appearance by cross section, PVL have a serpentine, longitudinal aspect, which can be challenging with regards to wire and catheter crossing, and in obtaining an effective seal with self-expanding devices. In contrast to the PVL around the annular ring of surgical valves, TAVR associated PVL presents a somewhat different anatomical situation. Although the PVL occurs at the native annulus, the metal stent frame creates a tubular channel within the aortic valve sinus that can affect PVL crossing and device deployment.

The successful closure of PVL around balloon TAVR valves has been previously reported using the Amplatzer Vascular Plug (AVP) 2 (St. Jude Medical, Minn, MN) [3], but Feldman and colleagues present the first reported case series using the AVP-4, an off-label use of a device approved for embolization of peripheral arteries or veins. Positive results have been reported by others for using the AVP-4 for PVL closure in self-expanding TAVR valves [4]. This device seems well suited to the task of percutaneous closure of PVL after TAVR, as it has a low crossing profile and the larger mid body of the device can be positioned entirely in the small space between the native valve sinus and stent frame to avoid embolization. The tapered ends of the device appear less likely to abut the left ventricular outflow track, or interfere with the prosthetic leaflets or coronary ostia, than other devices with large discs on the ends. The low crossing profile of the AVP-4 also allows for easier crossing of the PVL

with small 4F catheters, which makes the procedure more technically straightforward and reduces the risk for partial dislodgement of a transcatheter valve, which might occur if passage of a catheter were difficult. The limitation of the AVP-4 to small 4–8 mm sizes may be an issue since many PVL are closed with larger (> 10 mm) and often multiple devices; however, many PVL associated with TAVR are narrow and long, which may be why the shape of the AVP-4 and small delivery catheters are potentially advantageous in this clinical scenario.

The authors report the closure of PVL in six patients with moderate to severe regurgitation who had TAVR with the Edwards Sapien valve, reducing the regurgitation to mild to moderate in five patients. No explanation was provided as to why one patient did not have an echocardiographic or clinical improvement of the PVL. Real time three-dimensional transesophageal imaging was used to guide PVL crossing and assess the success of PVL closure, although the authors carefully, and appropriately, describe the limitations of echocardiographic and fluoroscopic imaging of the defects and regurgitant severity. The largest (8 mm) vascular plugs were used in all cases, without extension of the device beyond the valve stent margins. There were no complications directly related to the procedure, although no comment was made regarding hemolysis, which is a frequent, and nontrivial problem with PVL both before and after device closure. After a mean follow-up of 5 months, the five patients who had a reduction in the PVL regurgitation were doing well and free of heart failure symptoms. Long-term clinical and echocardiographic follow-up and larger patient series will be useful to guide more general adoption of this procedure.

The successful use of the AVP-4 for PVL associated with balloon-expandable TAVR valves represents an innovation in the treatment of patients with refractory heart failure due to severe PVL. With improved techniques for accurate valve sizing, redilation, use of a second higher or lower positioned valve, and new technologies that use an outer sealing cuff, clinically significant, severe PVL should become more rare. Nevertheless, over 50,000 TAVR implants have been performed in the past 10 years [5], and there are more than a handful of patients who have severe residual PVL post-TAVR who are challenging to medically manage. Even modest improvement in symptoms among these elderly, debilitated patients with refractory heart failure due to PVL would be greatly beneficial, and closure of PVL using vascular plugs may be the only option for them. Significant PVL following TAVR may be a matter for the history books in the very near-future, but until that point in time, the use of the AVP-4 as reported by Feldman and colleagues will have an important place in the PVL armamentarium.

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