Case Report

Paravalvular Aortic Prosthetic Valve Leak Closure: Technical Aspects of the Percutaneous Approach

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We describe the successful closure of an aortic paravalvular bioprosthetic valve leak with the simultaneous percutaneous deployment of two vascular plugs.

Key words:
Prosthetic paravalvular leaks, paravalvular defect closure, vascular plug II.

Manuscript received:
August 22, 2012;
Accepted:
August 2, 2013.

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Paravalvular leaks (PVL) are common following surgical valve replacement. Systematic evaluation with transesophageal echocardiography (TEE) revealed that paravalvular leaks with trivial or mild regurgitation are present at hospital discharge in up to 17.6% of all cases after aortic valve replacement and in 22.6% of all cases after mitral valve replacement.[1] The available data confirm that new regurgitant jets can develop during follow up, even without the occurrence of endocarditis.[2] Clinically significant paravalvular leaks that warrant repair occur in 1-4% of patients with prosthetic valves.[3]

It is well-known that heart valve reoperations are associated with a high but variable operative risk.[4,5] Percutaneous treatment of paravalvular prosthetic regurgitation has emerged as a safe and less invasive alternative, with feasibility demonstrated in case reports and two large series[6,7] but an estimated 64.5% 3-year survival, with mortality mainly related to the presence of significant residual paravalvular regurgitation and comorbidities.[8] In this study, one fourth of the patients were left with moderate to severe residual regurgitation and only one half had improvement of hemolytic anemia.

This procedure is infrequently performed and the technical information that is gained is very important for the future development of closure devices and the effective use of existing devices in paravalvular defect closure. Considering the increasing number of percutaneous aortic valve implantations, with their associated higher incidence of paravalvular leaks, it is likely that this procedure will become much more frequently performed.

Case presentation

A 71-year-old male patient, hypertensive, diabetic on oral medications, underwent coronary artery bypass surgery and aortic valve replacement for severe three-vessel disease and moderate aortic stenosis. The valve was a bioprosthetic Edwards Perimount 21 mm valve.

The patient improved significantly after the operation, but one and a half months later he was admitted to another hospital with pulmonary edema, after which he was incapacitated with dyspnea on minimal exertion. On transthoracic

echocardiography, he had preserved left ventricular function and an aortic prosthetic valve in a stable position, but with severe paravalvular regurgitation. A 2D transesophageal echocardiogram revealed a crescent shaped defect (Figure 1). There was no clinical or laboratory evidence of endocarditis.

A coronary angiogram demonstrated patency of the left internal thoracic artery to the left anterior descending artery, and patency of the vein grafts to the diagonal, obtuse marginal and right coronary arteries. An aortogram confirmed the presence of severe aortic regurgitation. Review of the 2D TEE revealed only one paravalvular jet through an oblong defect, on the posterior side of the non-coronary part of the ring. Based on the contour of the color flow at end-diastole, the defect was measured at 5-6 mm at its widest part and 14 mm at its longest (Figure 1). There was a space of at least 8 mm between the valve ring and the aortic sinus wall. We decided to close the defect percutaneously, with simultaneous deployment of two Amplatzer vascular plug II devices (St Jude Medical), 8 mm in diameter (Figure 2). Repeat surgery to repair the defect was an initial option, but with a Society of Thoracic Surgeons mortality score of 4.4%, and a mortality and morbidity score of 26.1%,[9] the cardiothoracic team insisted on a percutaneous approach.

The procedure was performed 5 months after the initial operation, with the patient under general anesthesia and the use of 2D TEE. The patient was premedicated with aspirin, clopidogrel and heparin, and antibiotics for endocarditis prophylaxis. The patient was in sinus rhythm with a complete right bundle branch block pattern on the electrocardiogram; a pacemaker wire was positioned in the right ventricle as a precaution. Two Arrow 7F 45 cm sheaths (St Jude Medical) were used for better support and were inserted through the right and left femoral arteries. Two multipurpose (MP) 6F guide catheters with the standard length of 100 cm (Launcher, Medtronic) were positioned through the paravalvular defect into the left ventricle using the child and mother technique, achieving a smooth transition and thus avoiding the edge of the guiding catheter catching on the rims of the defect. A multipurpose 5F angiographic catheter 125 cm in length (Cordis), was inserted into the 6F guide catheter over a 0.035" polymer-covered nitinol wire (Terumo Medical). We selected the multipurpose angiographic catheter for the posteriorly located defect, but depending on the location of the defect another tip shape could have been selected: e.g.

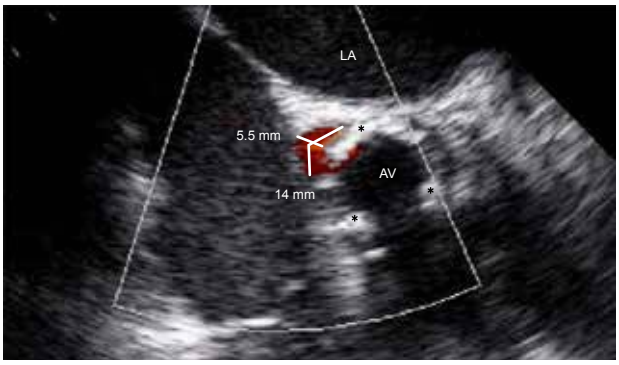

Figure 1. Two-dimensional transesophageal echocardiogram at the level of the aortic valve with color flow at end-diastole delineates a crescent shaped defect in the non-coronary part of the aortic ring. The defect was measured to be 5-6 mm at its widest part and less than 14 mm at its longest. The black asterisks mark the three struts of the bioprosthetic valve. LA – left atrium, AV – aortic valve.

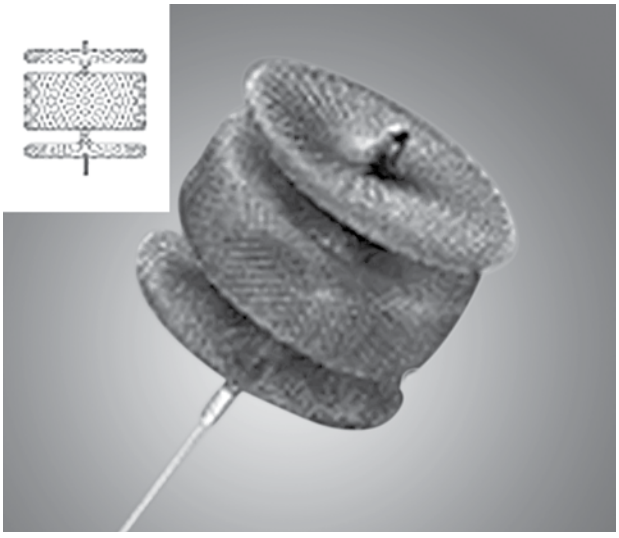

Figure 2. The Amplatzer Vascular Plug II device, which was used in our case, is cylindrical with discs on either side of the main part of the plug, each connected by a thin waist to the main part, permitting the device to be pulled against the valve ring.

Amplatz left or right. The defect was crossed with the two wires oriented posteriorly in the right anterior oblique projection, but the location of the wires outside the valve ring was verified in cranial views. The angiographic catheters were advanced into the left ventricle and, with the angiographic catheter and wire as support, the guiding catheters were telescoped one by one into the left ventricle, with no need for a stiffer wire support.

The two vascular plug II 8 mm devices were advanced one by one and the discs, the first of the three segments of the device, were deployed in the left ventricle. It is worth mentioning that the advancement of the device through the last part of the 6F guiding catheter was extremely difficult, possibly because of friction in the angulated part of the catheter or in an unapparent compression of the catheter at the level of the valve ring. One disk was pulled until resistance was felt and it was presumably anchored at one end of the defect. The device was fully deployed but remained under tension, until the other device was similarly fully deployed and then both devices were pushed. The 2D echocardiogram in multiple projections, with the devices still attached to their delivery cables, did not reveal any paravalvular regurgitation jets. Contrast dye injection through the guiding catheters revealed a small amount of leakage around the posterior device disc, the one that was fully deployed first, and leakage through the valve. After careful consideration the devices were released (Figure 3). A repeat aortogram revealed only mild aortic regurgitation. The 2D TEE, after the release of the devices, revealed only one small jet (Figure 4). No conduction abnormalities were observed during the procedure. The patient was discharged on aspirin and clopidogrel for at least a 6-month period.

A month later the patient remained asymptomatic and a new TEE revealed trivial paravalvular regurgitation. There was no laboratory evidence of hemolysis, with LDH levels and haptoglobin levels in the normal range and a stable hemoglobin level.

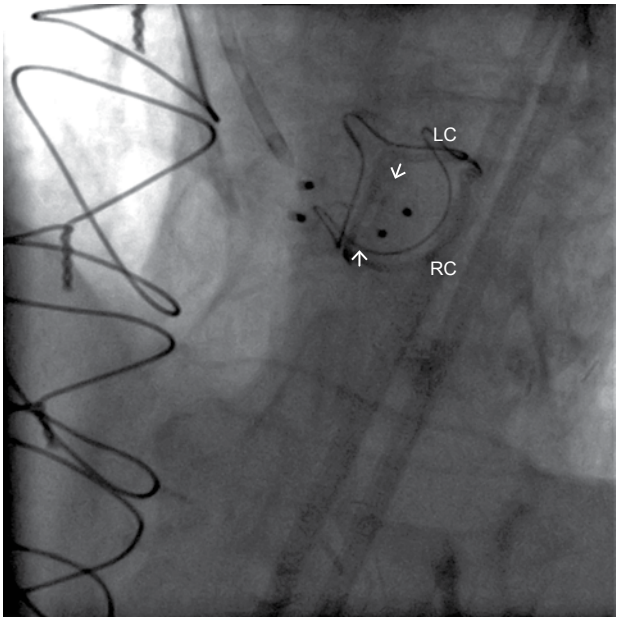

Figure 3. Right anterior and cranial view of the prosthetic aortic valve after deployment and release of the two 8 mm Amplatzer Vascular Plug II devices. The arrows point to the waist between the discs, on the ventricular side, and the deformed main parts of the devices, which close the defect. RC – right coronary cusp part of the ring; LC – left coronary cusp part of the ring.

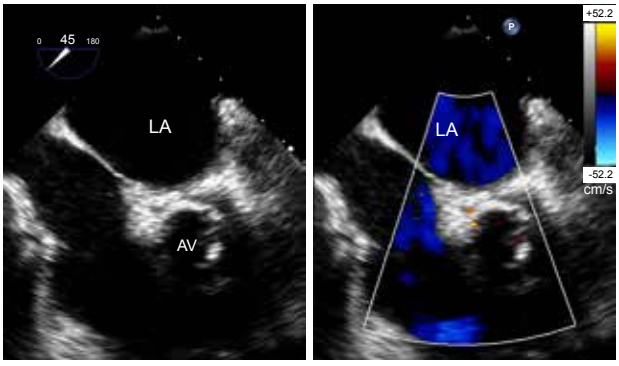

Figure 4. Two-dimensional transesophageal echocardiogram at the level of the aortic valve (AV) with color flow at mid-diastole, demonstrating a small residual paravalvular defect with trivial flow. LA – left atrium.

Discussion

The ability to close a paravalvular prosthetic valve leak percutaneously is very appealing to both the patient and the cardiac surgeon. Since its first inception by Hourihan in 1992,[10] an increasing number of published reports have demonstrated the feasibility of the percutaneous closure of these periprosthetic defects (Table 1). The devices that have been mainly used belong to the Amplatzer family of nitinol mesh occluders. These devices (atrial septal occluder, ventricular septal occluder, duct occluder, vascular plug II) are not designed for this specific task: i.e. plugging holes of different shapes between the edge of a prosthetic valve ring and the surrounding tissue, which is potentially prone to tearing. Nonetheless, in a large percentage of patients, the use of appropriately sized devices or multiple smaller devices resulted in a significant reduction of regurgitation and hemolysis,[6,7] with improved results over the follow-up period due to thrombosis and endothelization of the device.[22] On the other hand, in a number of patients, the results were not satisfactory, because of the device's inability to conform to the shape of the defect, or extension of the defect due to the cylindrical shape of the devices and their self expanding nature,[18,20] or worsening of hemolysis because of the high velocity

Table 1. Published reports of percutaneous aortic paravalvular leak (PVL) closures, mainly with the Amplatzer devices, including unsuccessful cases reported by surgeons. The number of mitral PVL closures is also included in the reports.

Author (reference)	Year	# patients	# leaks	Device/s	Clinical success
Hourihan[10]	1992	4	A (4)	Double umbrella	3/4
Webb[11]	2005	1	A (1)	Duct occluder	1/1
Pate[12]	2006	10	M (9)		
			A (1)	Duct occluder	1/1
Dussaillant GR[13]	2006	1	A (1)	Duct occluder	1/1
Hein R[14]	2006	21	M (13)		
			A (8)	Duct occluder - mVSD	8/8
Shapira Y[15]	2007	11	M (10)		
			A (3)	mVSD – pVSD	2/3
Hildick-Smith D[16]	2007	1	A (1)	mVSD occluder	1/1
Kahn A[17]	2008	1	A (1)	Vascular plug	1/1
Bairaktaris A[18]	2008	3	M (1)		
			A (2)	Duct occluder	0/2
Philips S[19]	2009	1	A (1)	ASD occluder	1/1
Castedo E[20]	2009	1	A (1)	Vascular plug	0/1
Alonso-Briales JH[21]	2009	8	M (4)		
			A (4)	Duct occluder	2/4
Hammerstingl C[22]	2009	1	A (1)	VPIII vascular plug	1/1
Neitlspach F[23]	2010	5	M (4)		
			A (1)	VPIII vascular plug	1/1
Smolka G24	2010	3	M (1)		
			A (2)	VPII vascular plug	2/2
Hoffmayer K[25]	2011	1	A (1)	mVSD occluder, VPII	1/1
Sharma M[26]	2011	1	A (1)	Duct occluder	1/1
Ruiz[6]	2011	43	M (38)	Duct occluder	
			A (11)	mVSD occluder VPIII vascular plug	8/11
Sorajje P[7]	2011	126	M (124)		
			A (30)	VPII vascular plug	22/30
Guzman MAP[27]	2011	51	M (57)		
			A (9)	VPIII vascular plug	9/9
Gökoğlan Y[28]	2012	1	A (1)	Duct occluder	1/1
Trayer T[29]	2012	2	A (2)	VPII vascular plug	2/2
			A (88)		71/88

M – mitral, A – aortic, mVSD – muscular ventricular septal defect, pVSD – perimembranous ventricular septal defect, ASD – atrial septal defect.

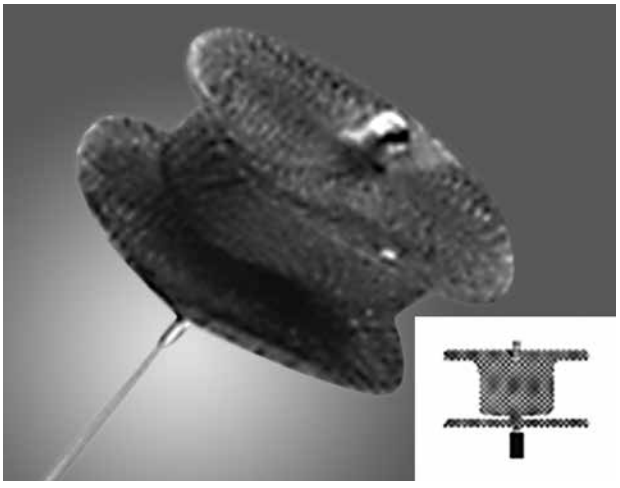

Figure 5. The Amplatzer Vascular Plug III device is oblong, with the disc on the ventricular side (retrograde deployment), protruding by 2 mm with no waist, imposing some limitations on device sizing.

jet crossing through the device or through a residual defect.[6,14]

A purpose-specific device, the Amplatzer vascular plug III (St Jude Medical) has been evaluated in a few patients, but has shown no clear clinical advantage over the other devices in the aortic position (Table 1). This device is oblong with short rims (Figure 5), better suited for crescent-shaped defects, but the deployment is more demanding because the device has to be oriented appropriately and larger delivery catheters are required; in addition the device is held in place mainly by compression of the body of the device by the rims of the defect, offering better sealing, with the danger of defect extension and unstable seating. The Amplatzer duct occluder and the ventricular defect occluder, with a similar mechanism of retention, have been used successfully, but have a stiffer and wider mesh and incorporate a polyester fabric.

The vascular plug II has a tight mesh with thin nitinol wires similar to the vascular plug III, but has a thin waist between the disc that holds the device on the ventricular side and a conformable body that plugs the defect from the aortic side (Figure 2). This provides more secure retention, probably with less danger of extending the defect, as compared to a device that expands inside the defect. The use of two devices side by side in crescent shaped defects, as seen in our case, requires smaller delivery catheters across the defect, may pose less of a problem in interfering with the valve function as compared to a single larger device, and seems to be effective in this type of defect. We opted to deploy the two devices simultaneously for three reasons: a faster procedure, a more symmetrical deployment of the devices, and avoidance of a step approach that would have made the selection of a second device difficult, without the availability of continuous 3D echocardiography.[23,25]

Conclusion

Percutaneous closure of paravalvular aortic prosthetic leaks with the Amplatzer vascular plug II, although not ideal, can be an effective and safe procedure, but one that requires meticulous preparation in selecting the size of the closure device. The simultaneous deployment of two smaller devices seems to be a fast technique that is well adapted to oblong defects.

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