Consortium-defined vascular complications: You say minor, I say major

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Transcatheter aortic valve insertion vascular complications have been defined and redefined by the Valve Academic Research Consortium. We present a case that points out a paradox with the current definition of a minor vascular injury.

CLINICAL SUMMARY

A 92-year-old woman presented with severe aortic valve stenosis, diabetes, severe chronic lung disease, previous stroke, New York Heart Association functional class II dyspnea, hemoglobin 10.8 g/dL, and a Society of Thoracic Surgeons predicted risk of mortality of 16.417%. Left ventricular outflow tract measurements included an area of 454 mm² and a perimeter of 78.5 mm. The iliac and femoral arteries all measured >8 mm in diameter and were without calcification.

The patient underwent transfemoral transcatheter aortic valve insertion through an open right external iliac artery access. Some resistance was noted during sheath insertion. Valve deployment went without apparent difficulty. The sheath did not slide out easily, but required some backward tension. Subsequent inspection of the sheath demonstrated that it contained a near perfect specimen of the external iliac artery (Figures 1 and 2).

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Upon identification of the vascular injury, the dilator and sheath were immediately reinserted over the wire, which had been maintained. There was no active bleeding. A right lower quadrant incision and retroperitoneal exposure were performed to expose the iliac artery. Despite the injury, there was no retroperitoneal hematoma. Vascular control was obtained, and a Dacron interposition graft was placed.

During all of this, the patient's electrocardiogram and hemodynamic characteristics remained entirely stable; furthermore, she required no inotropic support or blood transfusion. Three days later the patient was ambulating without difficulty with a hemoglobin level of 9.2 g/dL. She was discharged to a skilled nursing facility. At her 1-month follow-up, she was classified as New York Heart Association functional class II.

DISCUSSION

The Valve Academic Research Consortium-2 (VARC-2) consensus document defines a major vascular injury as "leading to death, life-threatening or major bleeding, visceral ischemia, or neurological impairment."¹ None of these events occurred in this patient. Is this, therefore, a minor vascular injury as defined by VARC-2 criteria? Had this unplanned vascular procedure occurred during the pivotal transcatheter aortic valve insertion studies done under the auspices of the first VARC consensus document, this case would have been classified as a major vascular injury.²⁻⁴

It is obvious that this case represents a major vascular injury related to transfemoral transcatheter aortic valve insertion. Newly planned studies may elect to use the updated VARC-2 criteria, and this may lead to confusion in grading of clinically significant vascular injuries. It is our opinion that vascular complications, much like death and pregnancy, are best classified with a dichotomous variable; that is, yes or no, rather than using mitigating

FIGURE 1. External iliac artery avulsion on sheath.

FIGURE 2. Close-up view of external iliac artery avulsion on sheath. The specimen represents the entire external iliac artery.

qualifiers such as major, minor, or presence of percutaneous closure device failure.

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Thrombosis following mitral and tricuspid valve-in-valve replacement

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There is a growing and robust experience demonstrating the safety and efficacy of valve-in-valve (VIV) implantation in the aortic position.¹ Mitral and tricuspid VIV implantation is also technically feasible with excellent acute outcomes.^{2,3} Sapien valve (Edwards LifeSciences, Irvine, Calif) thrombosis has been reported as a rare event following transcatheter aortic valve replacement (TAVR) in the setting of native valve aortic stenosis.⁴ We describe 3 cases of Sapien valve thrombosis following successful mitral (2 cases) and tricuspid (1 case) VIV

deployment and discuss the implications of these observations.

CLINICAL SUMMARY

The Intermountain Medical Center VIV experience includes 7 patients with failed mitral bioprostheses, 2 patients with repaired mitral valves utilizing mitral annuloplasty rings, and 2 patients with failed tricuspid bioprostheses. All transcatheter valves were successfully deployed and all patients were discharged from the hospital without significant adverse events. The immediate postprocedure mean transesophageal echocardiography (TEE) gradient across the Sapien valves was <5 mm Hg in all patients without more than trace valvular or paravalvular regurgitation. Three patients with valve thrombosis are highlighted in Table 1 and reviewed in detail below.

Patient 1

A 54-year-old man with a complex history of 2 prior sternotomies, including ascending aortic aneurysm as well as aortic and mitral valve replacements, presented with

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