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Commentary on Prosthetic Valve Dysfunction Post-Bevacizumab: A TAVR Thrombosis

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About the Study

The rapid expansion in the use of Transcatheter Aortic Valve Replacement (TAVR) across broadening patient groups such as lower surgical risk and younger patients, has brought to light the need for long-term device durability and safety. Although Clinical Valve Thrombosis (CVT) is an uncommon complication, when it does occur, it can result in dramatic hemodynamic deterioration and occasionally catastrophic events. Prosthetic valve thrombosis occurring late after valve replacement (greater than 90 days) is even more uncommon and presents a diagnostic and therapeutic difficulty. This is frequently considered to be due to patient or procedural differences, but the role of exogenous, non-cardiac factors including drug therapy remains under-investigated in the literature. This is an unleashing and significant report of late diagnosed TAVR thrombus onset, that developed temporally coincidental to the introduction of bevacizumab treatment, an extensively used drug that works as a VEGF inhibitor. This provides offers an important clinical signal, inviting further reflection on the impact of anti-VEGF drugs on bioprosthetic valves in patients.

A 69-year-old man with a history of CABG and surgical aortic valve replacement underwent successful valve-in-valve TAVR 10 years later due to severe aortic stenosis and high surgical risk. Prosthetic valve function remained hemodynamically stable with serial echocardiograms revealing normal leaflet motion and transvalvular gradients. At his 4th yearly annual follow-up post-TAVR, he was asymptomatic. He had a new 4/6 systolic murmur at the second right intercostal space on physical examination, approximately one month after starting intravitreal bevacizumab for age related macular degeneration. Echocardiogram reported evidence of prosthetic valve dysfunction with an area of 1.3 cm^2 and mean valve pressure gradient of 28.3 mmHg. Transesophageal echocardiogram also demonstrated thickened leaflets. Based on the close temporal relationship, Bevacizumab was stopped and anticoagulation was started in the inpatient setting, initially with intravenous heparin then with a transition to warfarin. After three months of treatment and discontinuing bevacizumab, the leaflet dysfunction resolved completely on repeat echo and the transvalvular gradient returned to previous baselines, providing further evidence of a reversible, thrombotic etiology rather than irreversible structural valve degeneration.

The time course of initiation of Bevacizumab and the development of prosthetic valve thrombosis, along with the prompt response to drug discontinuation and anticoagulation, argues for a reasonable temporal association and provides good circumstantial evidence for possible causality. Although the systemic bioavailability of Bevacizumab following intravitreal injection is thought to be low, there is increasing evidence that a degree of systemic absorption is enough to produce pharmacologic effects besides the eye. Bevacizumab's prothrombotic risk is widely recognized, especially in oncology, where it is associated with arterial and venous thromboembolism. Mechanistically, VEGF blockade by bevacizumab may disturb endothelial homeostasis. VEGF is essential to the maintenance of vascular health, increasing the generation of important antithrombotic mediators such as nitric oxide and prostacyclin.

Bevacizumab, by its VEGF inhibitory action, is also capable of shifting the fine balance between hemostasis and the procoagulant state to favor the latter, the anti-thrombotic factors released by the endothelium may be decreased and platelet activation favored. This systemic tendency towards thrombosis is especially worrisome given the bioprosthetic valve itself, where optimal endothelialization of the leaflet surface is important to reduce the potential for leaflet thrombosis.

On a clinical note, this report is of substantial clinical importance. It calls into question the assumption of systemic neutrality for intravitreal anti-VEGF agents, which are administered to millions of patients each year, some with cardiovascular comorbidities and bioprosthetic valves. This highlights the importance of a high index of suspicion for drug-related complications in patients with prosthetic valves and who develop new or unexplained valve pathology. It also underscores an important deficit in the published literature and in clinical guidelines. So far there has been a limited number of reports associating non-cardiac pharmacologic triggers with TAVR thrombosis, most probably due to underreporting rather than true lack of association. Considering the broad application of anti-VEGF medications and rapid rise of TAVR and valve-in-valve

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procedures in old patients, potential rare thrombotic events can become an important public health issue.

Our report is an important clinical signal that provides strong evidence in favor of a possible association between Bevacizumab and prosthetic valve thrombosis in a TAVR implant. The positive nature of the relationship is established based on a good clinical timeline, reliable diagnostic imaging and prompt response to therapeutic measures. Although causality cannot be established after a single report, the reported observation is physiologically plausible and we believe deserves attention of the medical community. The purpose of this report is to raise awareness among clinicians that local therapies may have potential systemic impact in susceptible patients. Clinicians need to have a high index of suspicion until further evidence from larger-scale pharmacovigilance studies is available and a better relative magnitude of risk is reported in registry analyses. For patients with bioprosthetic valves and on anti-VEGF agents, physicians should continue with serial annual echocardiographic examination.

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