Very late scaffold thrombosis in Absorb BVS: association with DAPT termination?

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ABSTRACT

Objectives

To shed light on the occurrence of very late scaffold thrombosis (VLScT) in patients treated with the Absorb bioresorbable vascular scaffold (BVS) and the possible association with termination of dual antiplatelet therapy.

Background

Multiple studies have proven feasibility and safety of the Absorb BVS. However, more recently, concerns were raised regarding the higher incidence of VLScT.

Methods

A viewpoint was created by a brief description background literature and three VLScT case descriptions.

Conclusions

Based on our case series and previous publications, we encourage prolongation of DAPT beyond 12 months after implantation of BVS.

The Absorb bioresorbable scaffold (BVS, Abbott Vascular, Santa Clara, California, USA) is a new promising treatment option for coronary artery disease to overcome limitations of metal drug eluting stent and is widely investigated. [1] Lately, concerns were raised regarding the occurrence of very late scaffold thrombosis (VLScT) in patients treated with BVS. [2] The ABSORB II randomized controlled trial (RCT) reported a disturbing number of six VLScT in 335 patients at three years follow-up. None of these patients were using dual antiplatelet therapy (DAPT) at time of the event. [3] Two-years results of the ABSORB Japan RCT described 4 cases of VLScT; two out of four patients had terminated DAPT. [4] These findings stimulated us to investigate the occurrence of this very late event and its relation with DAPT termination.

In our daily practice of three regional centers, we also have encountered cases of VLScT after discontinuation of DAPT. At 18 months, three of the four VLScT in a cohort of 685 patients seemed to be closely related to DAPT discontinuation. These cases occurred within 35 days after DAPT termination, which we believe needs the attention of the medical community.

A 60-year old female with risk factors dyslipidemia, hypertension, history of percutaneous coronary intervention (PCI), presented with stable angina pectoris and angiography revealed one-vessel disease of the RCA. Treatment consisted of pre-dilatation, implantation of 3 overlapping BVS and post-dilatation. Patient was using aspirin and clopidogrel for 369 days. Ten days later, she presented with STEMI with visible thrombus on angiography, which was treated with thrombectomy, drug-eluting balloon and abciximab.

A 63-year old male without cardiac risk factors was admitted with a STEMI due to an occluded mid-LAD. After thrombectomy, he underwent primary PCI with 2 overlapping BVS and post-dilatation. Ticagrelor was stopped at day 381 days and 35 days thereafter, this patient presented with STEMI due VLScT. Intravascular imaging revealed clear thrombus and minimal malapposition. Thrombectomy, stenting with everolimus eluting stent, and post-dilatation were performed.

A 50-year old female with positive family history for CAD and a current smoker was admitted to the hospital with a STEMI. After thrombectomy and pre-dilatation, she underwent PCI of the RCA with 1 BVS. Post-procedural OCT revealed malapposition and therefore, post-dilatation with a 4.0 mm balloon was performed reducing malapposition but unfortunately not eliminating this. At day 449, twenty days after prasugrel was terminated, the patient returned with a Q-wave STEMI due to angiographically and OCT proven ScT and malapposition. Treatment consisted of rePCI with thrombectomy, balloon angioplasty and Gp IIb/ IIIa inhibitor.

These cases were reported to draw attention to a problem that is becoming more common: VLScT. In our cohort and in the ABSORB II trial, no VLScT occurred in patients continued DAPT for a longer period of time. Based on this experience and previous

publications [4], we encourage prolongation of DAPT beyond 12 months after implantation of BVS, likewise as has been demonstrated to be efficient for high-risk DES-treated patients with a low bleeding risk [5]. A DAPT score ≥ 2 seems optimal for current DES whereas an increased risk of ischemic events for first generation DES would warrant an additional point [6] and this could theoretically apply for first generation BVS. Extending DAPT even longer, to 30 months as investigated by the DAPT study in DES patients, will cover the majority of time period before the resorption process of BVS is completed. [7] More data and dedicated studies are needed to confirm this recommendation. We believe that, considering inherent difference between BVS and metallic stent, probably specific DAPT recommendation is warranted for patients receiving BVS.

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