Bioresorbable vascular scaffold versus metallic stent in percutaneous coronary intervention: results of the AIDA trial

Syed Raza Shah\textsuperscript{a}, Mazia Fatima\textsuperscript{b}, Amin Muhammad Dharani\textsuperscript{c}, Waqas Shahnawaz\textsuperscript{d} and Syed Arbab Shah\textsuperscript{a}

\textsuperscript{a}North Florida Regional Medical Center, University of Central Florida (Gainesville), Gainesville, FL, USA; \textsuperscript{b}Department of Internal Medicine, Deccan College of Medical Sciences, Hyderabad, India; \textsuperscript{c}Department of Internal Medicine, Dow University of Health Sciences (DUHS), Karachi, Pakistan; \textsuperscript{d}Department of Internal Medicine, Agha Khan University Hospital, Karachi, Pakistan

ABSTRACT

Drug-eluting stents have significantly improved the long-term outcomes of percutaneous coronary intervention (PCI) by decreasing the excessive growth of neointima. However, conventional stents have some limitations. PCI with a bioresorbable vascular scaffold (BVS) has emerged as an alternative since the presence of the prosthesis in the coronary artery is transient. A US Food and Drug Administration advisory panel of experts recommended approval of BVS based on the analysis of its risks and rewards in July 2016. In June 2017, the preliminary results of the Amsterdam Investigator-initiateD Absorb Strategy All-comers (AIDA) trial were released. This randomized controlled trial compared an everolimus-eluting BVS with an everolimus-eluting metallic stent in the context of routine clinical practice. The preliminary results revealed no significant difference in target-vessel failure when BVS was compared with metallic stenting. However, during the 2 years of follow-up, BVS was associated with a higher rate of device thrombosis. This is seen as an important development in the trial. There are some concerns regarding stent thrombosis and the restoration of real vessel functionality in the long term. For these reasons, for now, metallic stents remain the treatment of choice for PCI.

Drug-eluting stents have significantly improved the long-term outcomes of percutaneous coronary intervention (PCI) by decreasing the excessive growth of neointima\textsuperscript{[1]}. However, conventional stents, which are metallic, cage-like structures, have some limitations; notably, they leave a permanent implant, which may prevent favorable arterial remodeling and preclude future surgical revascularization. In addition, the permanent presence of a metallic platform may impair the natural healing process of the coronary vessel wall, leading to a prolonged inflammatory response and poor clinical outcomes. PCI with a bioresorbable vascular scaffold (BVS) has emerged as an alternative since the presence of the prosthesis in the coronary artery is transient. This technology enables restoration of the normal vasomotor tone and allows positive remodeling, simultaneously reducing the trigger for persistent inflammation and facilitating further interventions by percutaneous or surgical means\textsuperscript{[2]}. Bioresorbable scaffolds were developed to overcome some of the disadvantages of metallic stents. Hence, the US Food and Drug Administration (FDA) Circulatory System Device Panel members reviewed the outcomes of the trial A Clinical Evaluation of Absorb BVS, the Everolimus Eluting Bioresorbable Vascular Scaffold in the Treatment of Subjects with de Novo Native Coronary Artery Lesions (ABSORB III) and additional post hoc analyses presented by the sponsor and the FDA\textsuperscript{[3,4]}. The FDA advisory panel of experts recommended approval of BVS based on the analysis of its risks and rewards in July 2016\textsuperscript{[5]}. In June 2017, the preliminary results of the Amsterdam Investigator-initiateD Absorb Strategy All-comers (AIDA) trial were released. This randomized controlled trial compared an everolimus-eluting BVS with an everolimus-eluting metallic stent in the context of routine clinical practice. The trial included 1845 patients undergoing PCI to receive either a BVS (924 patients) or a metallic stent (921 patients). The primary endpoint of the study was target-vessel failure, which included target-vessel myocardial infarction, target-vessel revascularization, or cardiac death. The preliminary results revealed no significant difference in target-vessel failure when BVS was compared with metallic stenting\textsuperscript{[6]}. However, during the 2 years of follow-up, BVS was associated with a higher rate of device thrombosis. This is seen as an important development in the trial. Although the full results of the study are yet to be published, the safety monitoring board recommended early reporting of the study results because of safety concerns.

The development of coronary artery stents was a major advance in interventional cardiology. Although...
the preliminary results for BVS are not very encouraging, it is still too early to draw conclusions. The AIDA trial is a landmark in the cardiovascular world. These preliminary results raise some concerns regarding thrombosis and the restoration of vessel functionality at long-term follow-up. However, we can learn some lessons from the AIDA trial. The use of thinner struts in such devices may minimize coronary blood flow perturbations and this could decrease the thrombogenicity of these devices. Newer devices should be used, with technical improvements that are supposed to ensure high shear stress and decrease blood flow separation with subsequent reduced platelet activation. Nevertheless, even with these improvements there are still some concerns regarding stent thrombosis and the restoration of vessel functionality in the long term. For the same reason, metallic stents remain the treatment of choice for PCI. However, larger studies with long-term follow-up are needed to adequately address the safety and efficacy of BVS use in such settings. It is anticipated that the results of the AIDA trial will soon be implemented in international guidelines.

Disclosure statement

No potential conflict of interest was reported by the author.

References

[1] Stettler C, Wandel S, Allemann S, et al. Outcomes associated with drug-eluting and bare-metal stents: a collaborative network meta-analysis. Lancet. 2007;370:937–948.
[2] Rzeszutko L, Depukat R, Dudek D. Biodegradable vascular scaffold ABSORB BVS™ - scientific evidence and methods of implantation. Postepy Kardiol Interwencyjnej. 2013;9:22–30.
[3] Chakraborty R, Patra S, Banerjee S, et al. Outcome of everolimus eluting bioabsorbable vascular scaffold (BVS) compared to non BVS drug eluting stent in the management of ST-segment elevation myocardial infarction (STEMI) - A comparative study. Cardiovasc Revasc Med. 2016;17:151–154.
[4] Jamshidi P, Nyffenegger T, Sabti Z, et al. A novel approach to treat in-stent restenosis: 6- and 12-month results using the everolimus-eluting bioresorbable vascular scaffold. EuroIntervention. 2016;11:1479–1486.
[5] Steinvil A, Rogers T, Torguson R, et al. Overview of the 2016 U.S. Food and Drug Administration circulatory system devices advisory panel meeting on the absorb bioresorbable vascular scaffold system. JACC Cardiovasc Interv. 2016 Sep 12;9(17):1757–1764.
[6] Wykrzykowska JJ, Kraak RP, Hofma SH, et al. Bioresorbable scaffolds versus metallic stents in routine PCI. N Engl J Med. 2017 Jun 15;376(24):2319–2328. Epub 2017 Mar 29.