Updated BRS Data: Safety Issues and Long-Term Benefit

Soon Jun Hong, MD, PhD

Department of Cardiology, Korea University Anam Hospital, Seoul, Korea

Second generation of drug-eluting stents (DES) has significantly reduced target lesion failure and in-stent restenosis (ISR) compared with bare metal stents (BMS). However, these stents leave a permanent metallic foreign body in the vessel, which may cause neoatherosclerosis, thrombosis, ISR and vascular inflammation. The metallic scaffold also impairs the coronary vasomotor functions. Bioresorbable scaffolds (BRSs) have been designed to overcome these limitations because they role as temporary scaffolding and then disappear. BRS may have several advantages over DES. The degradation of scaffolds can help restoring physiologic vasomotor function, late luminal gain, and late expansive remodeling. The absence of residual metallic foreign body can reduce the risk of stent thrombosis and the duration of dual antiplatelet therapy (DAPT). BRS are composed of either a polymer or metallic alloy. Polymeric BRS are mainly made of Poly-L-lactic acid (PLLA) or Poly-DL-lactic acid (PDLLA), and iron and magnesium based alloys have been under development. PLLA based Absorb bioresorbable vascular stent (BVS) (Abbott Vascula, Temecula, CA), DESolve (Elixir. Sunnyvale, CA), Fantom (Reva medical) and magnesium based DREAMS-2 (Biotronik SE, Berlin, Germany) have received a CE mark in Europe. The Absorb BVS have the largest amount of experimental and clinical evidences. At first, BVS was tested in the ABSORB cohort A, which demonstrated late lumen gain, and restoration of endothelial function at 2 years. Six randomized controlled trials (RCT) have compared the efficacy and safety of BVS with everolimus-eluting metallic stents (Xience): ABSORB II, EVERBIO II, ABSORB Japan, ABSORB China, TROFI II, and ABSORB III. Absorb III was the largest trial with two thousand and eight patients. There was no significant difference between the Absorb group and the Xience group in rate of TLF at 1 year. A recent meta-analysis of above 6 clinical trials reported no advantage for efficacy and a higher rate of subacute stent thrombosis in BVS group. Another meta-analysis of 24 studies demonstrated that BVS as compared with everolimus-eluting metallic stents was associated with higher risk for very late stent thrombosis (VLST) between 1 and 2 years. Potential mechanisms suggested in these reports are thick strut, high strut/artery ratio and weak radial strength of BRS. The PLLA based DESolve with thinner strut demonstrated no clinical event at 6 months. The Fantom BRS with tyrosine polycarbonate scaffold was tested in FANTOM II trial. Its unique radiopaque polymer makes the stents easy to deploy. Sirolimus-eluting absorbable magnesium alloy scaffold (DREAMS 2 G) was tested in the BIOSOLVE-II study. It showed that the six month in scaffold late luminal loss was 0.27±0.37mm and the TLF event rate 3% at 6 months. BRS is evolving despite recent concern about stent thrombosis. Development of newer BRS and implementation of technical deployment recommendation might allow BRS implantation closer to current DES efficacy and enhance the safety profile in near future.