

Reply to: Commentary to Josef Tacke, et al. The Randomized Freeway Stent Study: Drug-Eluting Balloons Outperform Standard Balloon Angioplasty for Postdilatation of Nitinol Stents in the SFA and PI Segment

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Thank you for your comment. In endovascular treatment of symptomatic peripheral arterial disease (PAD), the discussion whether to use primary stenting with bare metal stents (BMS) or with drug-eluting stent (DES) and when to use drug-eluting balloons is still open. In early days, numerous studies have demonstrated better short-term and mid-term patency rates of primary stenting as compared to balloon angioplasty (PTA) alone in the femoropopliteal artery segment [1, 2]. Later studies comparing PTA and drug-eluting stenting demonstrated the superiority of primary application of a DES [3]. However, the concern is well known that the implant of a foreign body into the artery may trigger smooth muscle cell growth and intimal hyperplasia. Therefore, the development of drug-eluting balloons and their excellent results were a major step forward in endovascular treatment of PAD. However, as you mentioned in your comment some studies have shown no difference between DEB and PTA in terms of patency rate, target lesion revascularization (TLR), and amputation rate at mid-term follow-up [4, 5]. And some studies have shown the superiority of DES as compared to DEB at mid-term follow-up of 3 years [6]. So obviously, the discussion is still open which endovascular strategy is best for patients with symptomatic PAD.

It has been shown in many DEB trials that flow-limiting dissections may occur and bailout stenting is required in up to 25% [4–6]. However, as you mentioned, the combined use of self-expanding stents and DEB may increase the risk of stent thrombosis due to delayed endothelial coverage.

At the time when the study protocol of the Freeway Stent Study was designed, no randomized trial of primary BMS followed by PTA versus DEB was published so far. Now the Freeway Stent Study has answered some open questions such as whether the use of a DEB after BMS application is useful and whether a DEB after BMS may increase the thrombosis rate. Of course more studies dealing with this topics are needed.

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