## **EDITORIAL COMMENT**

## Leaving Nothing Behind\*

Marc Bosiers, MD

Dendermonde, Belgium

First, I would like to extend my congratulations to Fusaro et al. (1) on their paper "Drug-Eluting Stents for Revascularization of Infrapopliteal Arteries: Updated Meta-Analysis of Randomized Trials."

## See page 1284

The authors address the issue of which devices, currently at hand, offer the best treatment for a focal below-the-knee (BTK) lesion. The meta-analysis concludes that for patients presenting with an infrapopliteal focal disease, primary stenting with a drug-eluting stent (DES) might be the primary approach. Treatment of these short lesions with a DES compared with a bare-metal stent or percutaneous transluminal angioplasty shows a reduced risk of restenosis, which is illustrated by the ACHILLES (Comparing Angioplasty and DES in the Treatment of Subjects With Ischemic Infrapopliteal Arterial Disease) (2), DESTINY (Drug Eluting Stents In The Critically Ischemic Lower Leg) (3), and YUKON-BTK (YUKON-Drug-Eluting Stent Below The Knee) (4) trials. In these trials, the average lesion lengths were 26.9 mm, 18.9 mm, and 31 mm, and the primary patency rates were 80.6%, 85.2%, and 80.6%, respectively.

In Europe, driven by cost-benefit analyses, we only treat focal BTK lesions in patients with critical limb ischemia, in whom patency is not the primary issue. This meta-analysis shows that primary stenting with a DES also has a positive impact on the risk of reintervention with an odds ratio of 0.31 (95% confidence interval: 0.18 to 0.54) and on the risk of amputation with an odds ratio of 0.50 (95% confidence interval: 0.26 to 0.97).

In line with the "leaving nothing behind" strategy, the drug-coated balloon might offer a better solution. It has been proven to work in the superficial femoral artery, but there is currently only 1 BTK trial. The DEBATE-BTK (Drug Eluting Balloon in peripherAl inTErvention For Below The Knee Angioplasty Evaluation) trial (5) reveals a 12-month primary patency of a promising 73% in lesions with an average length of 128 mm. These longer lesions correspond better to the daily infrapopliteal practice, where an isolated focal lesion in an otherwise healthy infrapopliteal artery is the exception. The vast majority of the lesions that we encounter in critical limb ischemia patients are long and diffuse. Intervention here with DES treatment makes no sense. First, there is a higher cost involved, and, second, if you perform only bail-out stenting with a DES, the long-term vessel patency is limited by the patency rate of the treated segment with percutaneous transluminal angioplasty only.

Probably the drug-eluting absorbable scaffold may be the best of both worlds. Its scaffolding support without a permanent metal implant can inhibit acute inflammation after implantation by its local drug release, avoiding the chronic physical irritation by absorption over time.

**Reprint requests and correspondence:** Dr. Marc Bosiers, Department of Vascular Surgery, AZ Sint-Blasius, Kroonveldlaan 50, 9200 Dendermonde, Belgium. E-mail: office@fmrp.be.

## REFERENCES

- Fusaro M, Cassese S, Ndrepepa G, et al. Drug-eluting stents for revascularization of infrapopliteal arteries: updated meta-analysis of randomized trials. J Am Coll Cardiol Intv 2013;6:1284–93.
- Scheinert D, Katsanos K, Zeller T, et al. A prospective randomized multicenter comparison of balloon angioplasty and infrapopliteal stenting with the sirolimus-eluting stent in patients with ischemic peripheral arterial disease: 1-year results from the ACHILLES trial. J Am Coll Cardiol 2012;60:2290–5.
- **3.** Bosiers M, Scheinert D, Peeters P, et al. Randomized comparison of everolimus-eluting versus bare-metal stents in patients with critical limb ischemia and infrapopliteal arterial occlusive disease. J Vasc Surg 2012;55: 390–8.
- Rastan A, Brechtel K, Krankenberg H, et al. Sirolimus-eluting stents for treatment of infrapopliteal arteries reduce clinical event rate compared to bare-metal stents: long-term results from a randomized trial. J Am Coll Cardiol 2012;60:587–91.
- Liistro F. Drug eluting balloon evaluation for below the knee angioplasty in diabetic patients with critical limb ischemia: the DEBATE-BTK study. Paper presented at; Transcatheter Cardiovascular Therapeutics; 24th Annual Scientific Symposium; October 2012, Miami, FL.

**Key Words:** drug-coated balloon ■ drug-eluting absorbable scaffold ■ drug-eluting stent(s).

<sup>\*</sup>Editorials published in the *JACC: Cardiovascular Interventions* reflect the views of the authors and do not necessarily represent the views of *JACC: Cardiovascular Interventions* or the American College of Cardiology.

From the Department of Vascular Surgery,  $\overline{AZ}$  Sint-Blasius, Dendermonde, Belgium. Dr. Fusaro Dr. Bosiers has reported that he has no relationships relevant to the contents of this paper to disclose.