AN INTERVIEW WITH…

# Sabine Steiner, MD

Dr. Steiner shares her take on current issues in femoropopliteal disease, including emerging data and ongoing research to improve results in this challenging anatomy.

**What do you believe is the biggest unmet need in peripheral vascular care?**

Overall, there is still a tremendous lack of attention to peripheral artery disease. Within the medical community, the clinical relevance, contribution to adverse health outcomes, and availability of various treatment options for peripheral artery disease are often neglected. Patients need easy access to appropriate disease management at every stage—from asymptomatic disease to critical limb ischemia—in order to improve their quality of life, tackle the excessive cardiovascular mortality, and reduce the socioeconomic impact of the disease.

**What are your thoughts on the recent findings from Katsanos et al,[1] and do they give you pause in any current investigations or in your clinical practice? Did the additional data presented at the Leipzig Interventional Course (LINC) affect your opinion?**

Let me be clear: We still have no definite proof of increased mortality with paclitaxel-eluting devices. However, in the meta-analysis of randomized controlled trials, Katsanos et al identified a strong signal for increased mortality beyond 1 year after femoropopliteal interventions.

This finding has to be taken seriously, and the intense discussion and presentations of various patient-level data analyses at LINC highlighted the importance of such a safety issue. So far, none of the clinical trials for drug-eluting technologies that I'm involved in have been halted, but they do aim to ensure rigorous, long-term follow-up to identify potential risks. I hope that the meta-analysis by Katsanos et al will actually translate into advances in the design of clinical trials in the field of peripheral endovascular interventions. It reminds me of the huge impact that a meta-analysis with a diabetes drug (rosiglitazone) had more than 10 years ago. Although the meta-analysis suggested an increased cardiovascular risk with rosiglitazone, this was not confirmed in a subsequent trial, leading to a lift of initial restrictions on the drug. This so-called rosiglitazone story was the rationale to mandate cardiovascular outcomes trials with new antidiabetic agents beyond showing an effect on glycemic control. In analogy to peripheral vascular interventions, we should learn from the scrutiny of drug trials and move forward from focusing predominantly on vessel patency in medical device trials for peripheral vascular interventions and focus more on patient-centered outcomes.

**What further investigation might these findings necessitate going forward, and are there any practices that can be taken to ensure patient safety in the meantime?**

As presented at LINC and, in part, already published independent individual patient-level analyses, reassuring safety outcomes for paclitaxel-eluting devices have been reported. It will be important to wait for full publications in peer-reviewed journals of these presentations as well as the findings of ongoing investigations of regulatory agencies to further clarify the issue. In the meantime, patients have to be informed of the risks and benefits of all available treatment options.

**If paclitaxel use in the superficial femoral artery (SFA) is proven to increase mortality risk, where do we look next for improved treatment options for this challenging anatomy?**

Vessel preparation is still a hot topic, but only limited outcome data are available. As we are treating more long, complex occlusions with severe calcification, aggressive use of scoring/high-pressure balloons and debulking devices is advocated but has to be evaluated in clinical trials. In the first-in-human ILLUMINA study, promising results were seen with the new sirolimus-eluting Nitides stent (Alvimedica, formerly manufactured by Carbostent & Implantable Devices SpA), which could also become an alternative to paclitaxel-coated stents.

**Can you give us some background on the REAL PTX study and how you think these recently published data[2] may impact clinical practice and future study?**

In the REAL PTX study, 150 patients with femoropopliteal lesions with stratification for length (≤ 10 cm, > 10 and ≤ 20 cm, > 20 and ≤ 30 cm) were randomly assigned to treatment with drug-coated balloons (DCBs) versus drug-eluting stents (DESs). More than half of the lesions were total occlusions, and the bailout stenting rate was 25% in the DCB group. Overall patency rates of around

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80% and freedom from target lesion revascularization > 90% at 12 months were promising, with comparable effectiveness and safety for DESs versus DCBs. A trend in favor of the DESs was observed at longer time points up to 3 years. Although good results in short lesions were sustained over time, restenosis rates were relatively high in longer lesions (> 10 cm) and chronic total occlusions up to 3 years, clearly indicating a need for improved technologies in complex lesions. Extensive vessel preparation might be one option to improve results, and we actually just started a subsequent trial named BEST SFA (NCT03776799), which is investigating the effectiveness of combining various devices for optimal SFA treatment.

**Do you see a future for bioresorbable stent technology for treating femoropopliteal disease? If so, in what time frame could it become a viable therapeutic option? Are there any other peripheral applications where this technology might be applied?**

The concept of bioresorbable stents still holds great promise by offering acute vessel support, limiting neointimal hyperplasia and late lumen loss over time, but ultimately disappearing and allowing the return of physiologic vasomotion. However, the high biomechanical stress in the SFA makes for high demands on fracture resistance and flexibility for mechanical scaffolds in general. To replace and compete with the advanced properties of modern nitinol stents, we probably need the development of a self-expandable bioresorbable stent with good deliverability. I assume it will take another 5 to 10 years before such a device could be introduced into clinical practice. As there is high interest in the development of a balloon-expandable bioresorbable stent for the coronaries, this could become an interesting option for infrapopliteal utilization as well.

**What is one thing your colleagues would be surprised to learn about you?**

Despite working in Germany, with its obsession for cars, I've never owned a car in my whole life. However, having grown up in a small village in the Austrian Alps, I'm a keen mountain biker and had many great bikes since my childhood, witnessing all new developments in this fantastic sport. ■

1. Katsanos K, Spiliopoulos S, Kitrou P, et al. Risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the leg: a systematic review and meta-analysis of randomized controlled trials. J Am Heart Assoc. 2018;7:e011245.
2. Bausback Y, Wittig T, Schmidt A, et al. Drug-eluting stent versus drug-coated balloon revascularization in patients with femoropopliteal arterial disease. J Am Coll Cardiol. 2019;73:667–679.

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