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Twelve-Month Results From the RANGER-SFA Trial

What these findings tell us about the safety and efficacy of the Ranger drug-coated balloon.

WITH DIERK SCHEINERT, MD

Twelve-month results from the RANGER-SFA trial were presented by Professor Dierk Scheinert, MD, at the 2017 Charing Cross Symposium in London, United Kingdom. Prof. Scheinert serves as Principal Investigator of the RANGER-SFA trial. The first-in-human RANGER-SFA trial is a multicenter randomized controlled trial evaluating the Ranger paclitaxel-coated percutaneous transluminal angioplasty (PTA) balloon catheter (Boston Scientific Corporation) for the treatment of lesions in the superficial femoral artery (SFA) and popliteal artery. The trial was designed to prove that the Ranger drug-coated balloon (DCB) is superior to uncoated PTA balloons as assessed by duplex ultrasound at 12 months postprocedure.

METHODS

The investigators enrolled 105 patients with femoropopliteal artery lesions at 10 sites in Germany, France, and Austria. Patients were randomized 2:1 to treatment with the Ranger DCB (n = 71) or to the control therapy (n = 34). Follow-up will be conducted through 3 years.

TWELVE-MONTH RESULTS

In the Ranger DCB group, 59 patients returned for 12-month follow-up. In the control group, the 12-month follow-up visit was completed for 28 of 34 patients. Patient and lesion characteristics were similar between the Ranger DCB and control groups. Technical and procedural success rates were also similar between the two groups.

At the Charing Cross Symposium, Prof. Scheinert reported superior 12-month primary patency and freedom from target lesion revascularization (TLR) rates for the Ranger DCB group as compared with the control group. The Kaplan-Meier estimate of the 12-month primary patency rate for patients treated with the Ranger DCB was 86%, which is significantly greater than that observed for patients treated with control balloons (56%). Likewise, freedom from TLR was greater for the Ranger DCB group than the control group at 12 months (Kaplan-Meier estimate, 91% vs 70%). Prof. Scheinert has previously reported that Ranger met its 6-month primary endpoint with significantly less late lumen loss (LLL) for the Ranger DCB group as compared with the control group.[1] LLL of +0.76 mm was observed at 6 months for the control group compared with -0.16 mm for the Ranger DCB group (P = .0017).

"The rates of primary patency and freedom from target lesion revascularization are amongst the highest observed in this type of first-in-man trials at 1 year. As a clinician, it is important to have a treatment option like the Ranger drug-coated balloon that exhibits consistent performance and outcomes; for patients, these attributes impact their quality of life, such as alleviating pain and discomfort, as well as reducing the probability of repeat procedures."

–Dierk Scheinert, MD
Professor of Angiology
Head, Department of Angiology
University Hospital Leipzig, Germany
Principal Investigator of the RANGER-SFA trial

The rates of adverse events and serious adverse events were similar in the two groups, with no target limb amputations and no deaths related to the device or procedure by 12 months. The investigators concluded that patients treated with the Ranger DCB demonstrated significantly higher rates of primary patency and freedom from TLR at 12 months versus patients in the control group. ■

1. Bausback Y, Willfort-Ehringer A, Sievert H, et al; RANGER-SFA Investigators. Six-month results from the initial randomized study of the Ranger paclitaxel-coated balloon in the femoropopliteal segment. J Endovasc Ther. 2017;24:459-467.