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Ranger Paclitaxel-Coated PTA Balloon Catheter Clinical Update

Recent early data from two studies demonstrate the promise of the Ranger DCB.

RANGER-SFA TRIAL

Six-month results from the RANGER-SFA trial were presented by Prof. Dierk Scheinert, MD, at CIRSE 2016, the annual meeting of the Cardiovascular and Interventional Radiology Society of Europe, in Barcelona, Spain. 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 balloon catheter (Boston Scientific Corporation) for the treatment of lesions in the superficial femoral artery (SFA) and popliteal artery. The trial seeks to prove that the Ranger drug-coated balloon (DCB) is superior to uncoated balloons at 6 months postprocedure in these lesions, as assessed by late lumen loss (LLL).

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.

Interim Results

In the Ranger DCB group (n = 71), 63 patients were available at 6-month follow-up (two patients withdrew and six patients missed their visits). In the control group, 6-month follow-up was completed for 25 of 34 patients (one patient died, two withdrew from the study, and six missed follow-up visits).

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 CIRSE, Prof. Scheinert reported that the study met its primary efficacy endpoint of in-segment LLL of the treated segment as observed by angiography at 6 months postprocedure, with significantly less LLL found for the Ranger DCB group as compared with the control group (Figure 1).

I was delighted to report the Ranger first-in-human results on behalf of the investigators. The impressive angiographic results are confirmation of the device's design goals and underpin ongoing studies of performance, including a real-world registry and, uniquely, a head-to-head DCB trial.

– Prof. Dierk Scheinert, MD
Principal Investigator
RANGER-SFA Trial

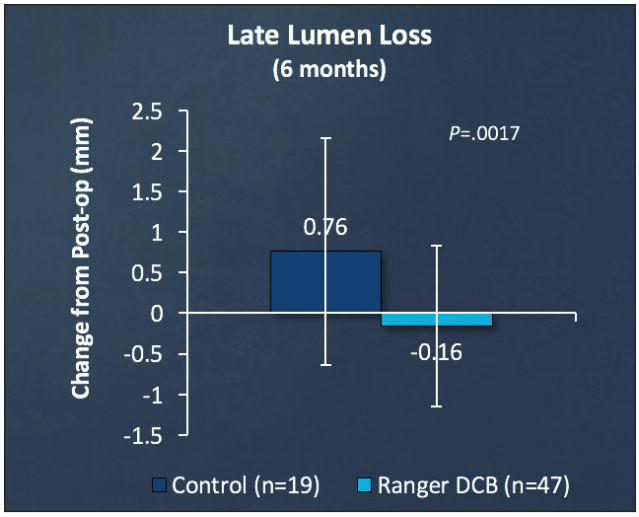

Figure 1. The primary endpoint was met with significantly less LLL for the Ranger DCB than for the control.

For the control group (n = 19) and the Ranger DCB group (n = 47), respectively, the minimum lumen diameters were: preoperative, 0.88 versus 0.79 mm (*P* = .92); postoperative, 3.3 versus 3.5 mm (*P* = .58); and at 6 months, 2.5 versus 3.5 mm (*P* = .0083), with postoperative to 6-month LLL of +0.76 versus -0.16 mm (*P* = .0017).

The secondary safety endpoint of cumulative target lesion revascularization (TLR) rate through 6 months was 12% for the control group versus 5.6% for the Ranger DCB group (*P* = .47). Prof. Scheinert noted that the Ranger DCB group achieved one of the highest reported rates (94.4%) of freedom from clinically driven TLR at 6 months; investigators are awaiting full 12-month follow-up data.

The rates of adverse events and serious adverse events were similar in the two groups, with no target limb amputations and one death in the control group at 6 months. There were no reported unanticipated serious adverse device effects. Additionally, in the Ranger DCB group, 81% of patients presented with no or mild symptoms (Rutherford class 0–1) at 6-month follow-up, and distributions for both control and Ranger DCB groups showed improvement, with a shift to lower Rutherford categories and no significant difference between groups.

In both groups, there was significant improvement in ankle-brachial index (ABI) and hemodynamic success at 6 months (*P* < .05). The mean rate of hemodynamic success (positive ABI change ≥ 0.1) was 76% for the Ranger DCB and 56% for the control (*P* = .1214). There were no significant differences between groups in terms of walking function or quality of life.

The investigators concluded that patients treated with the Ranger DCB demonstrated significantly less LLL at 6 months versus patients in the control group. Additionally, at 6 months, TLR rates trended toward separation between the Ranger DCB and control groups. Patients treated with the Ranger DCB demonstrated significant improvements in symptoms and hemodynamic success at 6 months.

RANGER ALL-COMERS REGISTRY

Interim results from the multicenter Ranger All-Comers Registry evaluating the Ranger DCB for the treatment of femoropopliteal atherosclerotic lesions were presented at the CIRSE 2016 conference. Michael Lichtenberg, MD, FESC, is the Principal Investigator for the registry.

Methods

The registry has enrolled 180 patients in Germany and Switzerland. Key inclusion criteria are patients with peripheral artery occlusive disease of the SFA—PIII and Rutherford class 2 to 5.

The primary efficacy endpoint is primary patency at 12 and 24 months, defined as freedom from ≥ 50% restenosis as indicated by duplex ultrasound peak systolic velocity ratio ≥ 2.4 in the target lesion with no reintervention. The primary safety endpoint is major adverse events, defined as a composite of device- or procedure-related mortality and major target limb amputation at 6 months.

The Ranger SFA Registry provided significant validation of the efficacy and safety of the Ranger DCB for patients with long femoropopliteal artery lesions.

– Michael Lichtenberg, MD, FESC
Principal Investigator
Ranger SFA Registry

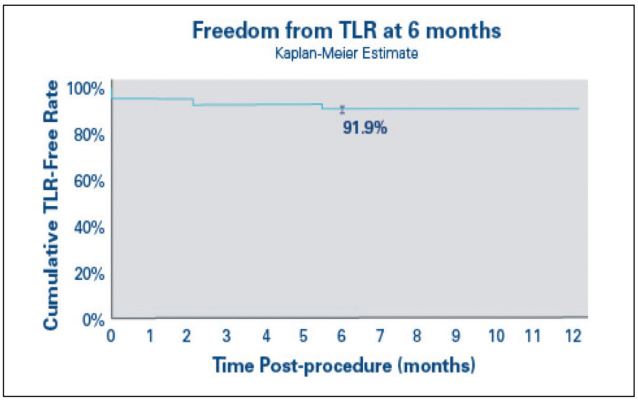

Figure 2. At 6 months, the rate of freedom from TLR was 91.9%.

Interim Results

Interim findings were presented on 149 patients and 210 lesions treated with the Ranger DCB. Mean age of the patients is 70 years, 63% are male, and baseline mean ABI is 0.6 (range, 0.01–1.43). Procedural outcomes included 73% technical success for DCB only (no flow-limiting dissection) and 100% success for DCB plus adjunctive therapy (stenting). Residual angiographic stenosis was 12%.

With 105 treated patients available at 6-month follow-up, 91% of treated limbs improved by one or more Rutherford categories and 80% improved by two or more Rutherford categories. There was statistically significant ABI improvement in treated limbs from 0.583 at baseline to 0.879 at 6 months (*P* < .01). At 6 months after treatment with the Ranger DCB, primary patency was 91.1% (Kaplan-Meier estimate) and freedom from TLR was 91.9% (Figure 2). ■