Title: LINC 23: RANGER II SFA: 3 Year Patency and 4 Year Clinical Safety
Participants: Dr Marianne Brodmann
Date: 15/06/2023

Dr Marianne Brodmann

“My name is Marianne Brodmann. I'm a vascular specialist, angiologist in Graz here in Austria at the Medical University, and we do a lot of interventional therapy in the PAD field. I have a very long experience with that.

Unique Features of the Trial

Regarding the Ranger SFA study, I’m referring to the Ranger SFA II study. I think the unique features of this study is that we evaluated a low-dose paclitaxel device. And I think that's very very important regarding all this paclitaxel safety issue. And there is a unique feature about this also because there was a long lesion cohort sub, cohort substudy with really a good number of patients with longer lesions, where we also could evaluate this low-dose paclitaxel coated DCB, and then there was also pharmacokinetic substudy, which has been reformed in the United States. But anyway, so the Ranger SFA II study has really a unique set-up, answering a lot of questions for the usage and the efficacy and safety of a paclitaxel-coated device. And in this specific case, a low-dose paclitaxel coated device.

Patient Population and Study Design

Evaluating patients with claudication. So, with Rutherford two to four and not critical limb ischemia. So that was the patient cohort, so claudication patient with claudication and rest pain, so Rutherford four with a certain lesion length, and then there was the long lesions subcohort.

Key Findings

The key findings were the long-term efficacy, so up to three years and then up to four years. And regarding this, in comparison to other studies out there, other, how to say, other data sets out there available, for example, IN.PACT and Stellarex, we were able to show that for the three year and for the four-year outcome with a low-dose paclitaxel coated device, we really had a very efficient outcome. So three-year outcome range are better than the ones I have already mentioned. Regarding clinical-driven TLR, and the same for the four-year outcome. For the four-year outcome, there was no difference anymore between this low-dose paclitaxel coated device outcome compared to a higher dose paclitaxel coated device outcome at four years. Regarding clinically driven TLR.

Patient Benefit from the Use of DCB

As I mentioned already before, we were able to show that a low-dose paclitaxel coated device in the Ranger long lesion subcohort was also able to treat patients with longer lesions in an efficient way regarding long-term outcome. And I think that makes me very

confident to use this in my real-world practice, because in real world practice, you usually have longer lesions.

Further Research Required and Next Steps

So, we already have the comparison and the compare study between low-dose and high-dose, the direct comparison between a low-dose paclitaxel coated device, the Ranger SFA, compared to a high-dose paclitaxel coated device, which is the IN.PACT. So, this is already done. I think what further research should be; DES compared to DCB, drug-eluting stent to drug-coated balloon in a larger amount as already data out there. And for sure the upcoming interest in the next years will be the direct comparison of paclitaxel coated DCBs to limus coated DCBs. We have in the meantime this Rona trial. We don't know the outcome data so far. They will be presented maybe at the end of the year. But anyway, I think that will be the utmost or the biggest interest in the future. That's just my personal impression.

Take-Home Messages

Low-dose paclitaxel coated DCB can produce good long term outcome data with a high value of safety."