- So my name is Marianne Brodmann. I'm here working at the Medical University of Graz, Austria. I'm the Head of the Vascular Medicine Department, the Department of Angiology. And I focus with regard to my research on endovascular therapy in patients with PAD.

Device

So the topic of the talk today is the RANGER II SFA trial, the randomised controlled study, and the results in women, patients with occlusions, and severe calcifications. The Ranger™ DCB is a low-dose paclitaxel-coated DCB with only two micrograms per square millimetre paclitaxel on the surface of the balloon. So it's a low-dose paclitaxel-coated balloon, and therefore it's very necessary to show the efficacy data of low-dose DCB in comparison to other competitors which are on the market, which are usually high-dose paclitaxel-coated balloons. So if such a DCB is showing efficacy also in the long-term, this is very important for us, as we do not need, as endovascular physicians, we do not need that much paclitaxel per patient.

Study Design and Patient Cohort

The study design is a randomised controlled study, meaning that we compared the Ranger DCB to an uncoated balloon, and it was a cohort with purely claudicant above-the-knee disease. And we have now also subgroup analysis for different subgroups. And as already mentioned for women, for CTOs, and severely calcified lesions, which is the issue of this talk, that in this subgroup, we evaluated a low-dose paclitaxel-coated DCB for efficacy and safety.

Key Findings

The key finding is that although in a really complex patient cohort, meaning women, because they have usually smaller vessels, CTOs, which is usually difficult to treat, and severely calcified lesions, which is also a treating challenge, the low-dose paclitaxel-coated Ranger DCB showed really great data, and can be compared to others in the market, meaning high dose DCBs, really showing good efficacy and safety for the long-term.

Which Patients would Benefit from this DCB

I would suggest to use the Ranger™ DCB in all kinds of patients, also in complex patients as this subgroup analysis is showing because it's not only safe to use the low dose, but it's also very efficient for the longer term follow-up. And I think this is really very helpful for us. So you can use this kind of DCB, the Ranger™ DCB as a regular DCB for every patient you want to treat.

Take-Home Messages

So the take-home message would be from my point of view, that the low-dose paclitaxel-coated balloon can produce really efficient long-term outcome data. And there's also a very favourable safety profile which can be achieved with a low-dose paclitaxel-coated balloon in the long term.