- My name is Marianne Brodmann. I'm from the Medical University of Graz in Austria. I am the Head of the Department of Vascular Medicine, Angiology as it's called here in Austria. And I'm focused on endovascular therapies in patients with PAD. This is my main research area.

Study Design and Patient Population

So with regard to the IN.PACT global study, this was a global study registry, where we included all kinds of patients with PAD and above-the-knee disease, who had either Rutherford 2 to 4, but we also included some Rutherford 5 patients. And is it a real world registry with a lot of sites all across the world, representing the patients really needing endovascular therapy. And we evaluated the IN.PACT Admiral Drug-Coated Balloon in this real-world patient cohort, which is in my opinion, more representative at the end of the day than a randomised controlled study, because it shows the patients we are treating every day. And with regard to this, we were able then to have some subgroup analysis in the IN.PACT global study, and this is really very helpful for us in our daily practise.

Importance of this Cohort

Why was it important to look at this cohort, especially about the cohort of females and diabetics, is that females are usually underrepresented in all kinds of trials. Why this is the case, especially for above-the-knee disease with claudicants, females more often show up in the different hospitals at a more diseased stage of the disease. So a lot of females present the first time with critical lymphocemia. And in all the trials with claudicants females are underrepresented. The percentage of females is usually around 30%. So it's very important to look at the female cohort, because females also have usually worse outcomes than males because they have smaller arteries, and as I have already have pointed out the disease is already at the more aggressive stage. And with diabetics, this is another issue, because diabetics usually have worse runoff, and therefore also worse outcomes with regard to the endovascular treatment, and the population of patients with diabetes is increasing worldwide. And therefore we have more and more diabetics in our trials, and more and more diabetics where we need to do endovascular therapy. Therefore these two cohorts, subgroup analysis of these two cohorts is so important.

Key Findings

The key findings were that with regard to the female sub-cohort and the diabetic sub-cohort, the outcome with regard to the treatment, especially the long-term outcome, with regard to the treatment with the IN.PACT Admiral DCB was fantastic. So females and diabetics have a better outcome if they are treated with a drug-coated balloon than before. And this is really encouraging and very helpful for us for the future, as we face more and more patient groups where we need to do endovascular therapy with regard to females and diabetics.

Conclusions

From this data, the conclusions which can be drawn and made, in females and diabetics, a drug-coated balloon is very efficient. Also with regard to long-term outcome, with sustained long-term outcome. And it's safe. We didn't see any safety signal because still at this stage we have to discuss the Paclitaxel safety issue. And that's the point. In this IN.PACT global study in total, we didn't see the safety issue, which has been reported by Katsanos in 2018. And in this real-world registry with a patient cohort like females and diabetics, who very often have a lot of co-morbidities, and therefore might have worse outcomes, we didn't see any safety signal. So Paclitaxel-coated balloons in females and diabetics are safe and very efficient.

Take-Home Messages

I would conclude this interview with a take-home message that in more and more complex patients, in females and diabetics, especially females with the smaller vessels, and diabetics with worse runoff are a really complex patient cohort. In this complex patient cohort, I feel very confident to use the IN.PACT Admiral DCB, because it really shows no safety issue, in the long-term follow-up, and shows really a highly efficient outcome also for the long-term follow up.