Title: SUCCESS PTA: SELUTION SLR DEB in Peripheral Arterial Disease
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Date: 13th September 2023

Dr Michael Lichtenberg

" My name is Michael Lichtenberg from Arnsberg Vascular Centre. I'm an interventional angiologist and today I would like to report and discuss a little bit about the SUCCESS registry analyzing efficacy and safety of the Selution drug-eluting stent.

Reasoning Behind the Study

So, the Selution drug-coated balloon technology is based on sirolimus drug-coated balloon technology. And of course for this special DCB for treatment of peripheral artery disease, efficacy and safety analysis need to be performed. First-in-man data were already reported. A randomized control trial is underway in the United States and besides that, a prospective multicenter registry was organized to analyze safety and efficacy of the Selution drug-coated balloon for peripheral artery disease, including SFA and popliteal, as well as BTK treatment indication to analyze safety and efficacy of sirolimus drug-coated balloon technology.

Patient Population and Study Design

So, it's a multicenter prospective registry analyzing safety and efficacy of distribution drug-coated balloon for SFA and BTK lesion. It was conceived, or is conceived as an all-comers registry. So, very broad inclusion criteria and a very narrow exclusion criteria, Rutherford two to five were allowed in this trial. Lesion length, no restriction. This means that all lesion lengths could be included in this trial. All combination therapy, meaning lesion preparation technology, atherectomy scoring, angioplasty, stenting tech implementation, all these combination therapy is allowed in this multicenter trial, which gives us hopefully more data for combination therapy of drug-coated balloon angioplasty plus adjunctive therapy.

And it's very good to see also that the BTK indication is included in this prospective registry, meaning also all indication for BTK in this treatment can be included in this registry. Meaning given that this gives us the opportunity to gain more experience with sirolimus drug-coated balloon technology for BTK indication.

Key Findings

So, we just reported on interim data, meaning six months interim analysis, key factor, key points here, very low target lesion revascularization rate of a little bit less than 5%. This was very surprisingly positive, I must say, especially as the target lesion length was around 140 millimeters. So we treated really all-comer patients, patients which showed up in the clinic. Again, all lesion lengths were allowed in this treatment and having a low revascularization rate after six months in this interim analysis was very surprisingly positive. So this gives hope. And yeah, we will present interim twelve-month data in a couple of weeks in Copenhagen at CIRSE Congress. And yeah, I'm looking forward to present as well very positive data here.

Take-Home Messages

We are having now a very good option with this new generation drug-coated balloon technology. Sirolimus technology seems to be very effective and safe. The safety aspects like in the past with peripheral embolization issues of paclitaxel, meaning occlusion of microcirculation outflow was not so far reported as an issue in this all-comers registry after interim analysis. I think this is very positive to see and also for efficacy, these very promising low target lesion revascularization rate is very helpful I think, especially in patients with complex disease. So a very promising new technology. So the next step is, of course, to get all the 722 patients in this trial. We are close to that, we have around 90% inclusion now. We are absolutely on time with that, as per our perspective. So we hope to finalize inclusion within this year and then, of course, we start with analyzing the outcome, efficacy, and safety of all patients. And I'm very positive that we will have very good data ahead of us."