Title: CIRSE 23: BIONETIC-TRA: DyNETIC-35 Stent for Iliac Lesions
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Dr Michael Lichtenberg

"My name is Michael Lichtenberg from Arnsberg Vascular Centre in Germany.

Reasoning for this Study

More and more interventions can nowadays be performed via a transradial access, meaning we do not need to put the patient in the hospital for a couple of days, meaning we can do an intervention via transradial access and analyse efficacy and safety for transradial access for especially iliac intervention. So we want to learn how we can implement this in our daily routine and we also wanted to learn how the existing technology and in this case the Dynetic stent from Biotronik helps us to do transradial interventions of iliac lesions.

The Dynetic-35 Balloon Stent System

We aim to include 25 patients with multiple indications for iliac artery intervention, meaning stenosis, occlusions, complex occlusions of both iliac arteries. So multiple indications in patients with Rutherford three to five having just an iliac artery, a lesion or occlusion. At the moment we have already 15 patients included. We just started with this registry and as an interim analysis after twelve patients I can say we had very good outcomes in terms of safety issues. No problems occurred, especially with transradial access, no bleeding complication or any bailout procedures which could have been thought of for transradial iliac arterial intervention. So also very effective, but it's just an interim analysis. We want to include 25 patients and of course also evaluate the efficacy in terms of patency rate after twelve months for this Dynetic stent.

Study Design

So it's a monocenter prospective or commerce registry in patients with just iliac artery lesions, meaning that they shouldn't have any additional fem-pop lesions. As we are aware that we don't have so many devices on the market in Europe which help us to perform transradial interventions also of the fem-pop area. So we need longer shaft balloons and stents. This is at the moment not available for DSFA popliteal artery, so therefore we just concentrate on iliac artery lesion treatment.

This interim analysis which we just performed after twelve patients, meaning 50% of the patients included, showed a very good efficacy rate of these after six months, no restenosis or reocclusions. All patients, all the indications we included in this registry could be treated via transradial access. No complications in terms of radial access complication, including occlusion of the radial artery or bleeding complication occurred. We did not have any issues with reaching the iliac artery from the left side. This means of course we need to do a very good screening of the patient in terms of underlying subclavian artery access issues or radial access issues. So a good screening is very important for good success.

Take-Home Messages

So I think the future of peripheral artery disease treatments will definitely more and more from transradial access safe, it's effective, patients can be sent home very soon after the intervention. So our aim is also to perform an economic analysis after the inclusion of these 25 patients. Therefore, I think more and more lesion treatment in patients with peripheral artery disease can be performed in outpatient department, something we already see in the United States in [indistinct]. And I think we can definitely copy this and do more and more peripheral artery disease interventions via transradial access.

Next Steps

So the next step is of course, to get all the 25 patients into the study. We are close to that and yeah, we'll then perform a twelve-month safety and efficacy data analysis and then of course we'll report on that."