Title: LINC 23: TINTIN: Combination DCB and Bare Metal Stents In PAD: 4 Year Outcomes
Participants: Dr Koen Deloose
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Dr Koen Deloose

"So, Hello. I'm Dr Koen Deloose. I'm the head of the Department of Vascular Surgery in AZSint Blasius Dendermonde in Belgium and I would like to talk to you about the 48 months results of our TINTIN trial, a physician-initiated trial that we performed with the Luminor drug-coated balloon and iVolution stents.

Reasoning Behind This Trial

The reasoning behind this trial is actually very clear. On one side we are living with the leaving nothing behind adagio. But I realized in daily life, in my daily life, my daily practice, that leaving nothing behind remained a dream. And so that we need the more complex, the longer, the more calcified, the more occluded the vessel is, the more scaffolds we need. And I really wanted to study, especially in very complex task C and D lesions. I wanted to study if the combination of an efficient drug-coated balloon already proven in a lot of studies and data that the efficiency, and efficacy of a drug-coated balloon combined with an efficient scaffold, that this is offering better results in this very complex task C and D lesions.

The Luminor DCB and the iVolution Self-Expandable Stent

On one side we have the Luminor, the Luminor that already has proven its efficacy and safety in, for instance, the FPAC trial, a randomized controlled trial with tremendous freedom from clinically driven TLRs, more than 90% at three and four years and very high primary patency rates. Of course, in the FPAC randomized controlled trial, like in a lot of these ideal circumstances RCTs, we noticed a lesion length of around six centimetres. I don't see lesions of six centimetres in my daily practice. On the other hand, we have also results with the iVolution scaffold, the nitinol stent, but on the relatively short-term, one-year, two-year follow-up. But I wanted to be sure also we

noticed in a lot of trials that when we are facing more complex lesions that these nitinol stents, that they have a little bit - the problem of durability. So, after a couple of years, two years and more, you see the efficacy dropping tremendously. And so, I wanted to see that - if we are combining the efficacy on the longer term of the FPAC trial device, the Luminor, combining with a very good scaffold what was proven on the shorter term in the iVolution study. So, combining these two, if this is also on the longer term, an efficient and safe way of treating complex fempop lesions.

Patient Population and Study Design

So, the study design is of the TINTIN trial, is a prospective, non-randomized, single arm, multicenter physician-initiated trial where we are investigating 100 patients in complex task Cand D femoropopliteal lesions and testing this combination as we discussed Luminor, drug-coated balloon and iVolution stent, 100 patients, tasks C and D. And if we are looking at the patient characteristics and the lesion characteristics, you see that we are studying a real-life population. Mean lesion length in the cohort was 24 centimeters.60% were CTOs.28% of the patients were real CLTI patients, Rutherford four, five and six. So that's a real cohort of daily based, daily practice vascular patients. And we studied the combination of both devices in this challenging population.

Key Findings

So, I had the honour to present at LINC 23, I had the honour to present the 48-month results, so four-year results in these complex lesions, complex patient cohort. And so, the first finding we had was that at 48 months, 36 patients out of our hundred enrolments died already. So, it's a clear sign. It was reflected in the survival curve in the Kaplan-Meyer analysis survival rate curve in a survival rate of 61% after four years. So again, another signal of how diseased this category of vascular patients is 61% survival rate. If we make the shift analysis critical limb ischemia patients versus claudicants. We notice that at four years, the survival rate was72% in the claudicants and 43% in the CLTI patients. So, it means that more than half of our CLTI patients after 48 months are dead. On the other hand, I need to say that the combination of this Luminor combined

with iVolution stent is really a good combination in these challenging lesions we reached a freedom from clinically driven TLR at 48 mounts of74.8% if we are looking at the clinical assessment. Also, there I noticed that the shift we've made during the procedure from Rutherford, five, four and three towards two, one and zero, then this is still sustained up to 48 months. And the same findings were there a sustainable result at 48 months. Concerning the ABI measurements so in general, very diseased population, relatively bad survival rates - expected according to literature, but on the other hand, a very safe and efficient combination. Also, on the longer term of this iVolution and Luminor drug coated.

Take-Home Messages

The take-home message in fact of the TINTIN trial is very clear first point survival rates in very diseased vascular patients are bad in our series 61% after four years. Second take-home message, if you are facing very challenging, complex tasks C and D lesions, occlusions, heavily calcified lesions, then you need a scaffold on one side, but you also need to have durability, a drug-eluting on the other side. Right up to now, it is paclitaxel. We don't have sufficient data with other drugs, and the Luminor is a perfect example for this. And then, finally, if you are, let's say, comparing the findings in the TINTIN trial with some other trials. And I know that it is just for educational reasons and not scientifically perfectly correct. But if you are comparing with other studies benchmarking with other studies like the Eluvia Long Lesion Registry of Munster, like the Silver Pass results, both cohorts, like the global results with the Admiral drug coated balloon of Medtronic long-lesion subcohort notice that the combination of scaffolding and drug elusion is still a perfect winner in these difficult and complex lesions.

Further Study Needed

Well, of course, like I've mentioned in the beginning, we are speaking about a single-arm study over here. So, I would love to see a randomized study in the same complexity of lesions and patients were randomized study on one side drug-coated balloon combined with a bare metal stent scaffold versus drug-eluting stent. And I want to see

which one is the safest is the most efficient one. Not only in the very short, easy, straightforward, randomized, controlled trial lesions, but also in the real-world lesions."