**Title: CIRSE 22: EFFPac Trial: 5-Year Results of Luminor Drug Coated Balloon in Pts With Peripheral Arterial Disease**

**Participants: Prof Ulf Teichgräber**

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**Prof Ulf Teichgräber**

" - Hello, my name is Ulf Teichgräber, I'm a professor of Radiology and specialise in interventional radiology, and I'm the chairman of the Department of Radiology in Jena University Hospital, which is in Thuringia, Germany, right in the heart of Germany.

**Study Rationale**

Well, this trial is a multicenter randomised controlled trial. This is performed by me as principal investigator, and initiated as investigator initiative trial. So, that means that the investigational product is actually a commercial product, but it is independent of the manufacturer. So, and the responsibility for the trial, and its conduction lies within my university hospital. 11 centres have participated in the EFFPAC trial. And the rationale behind it is to see to assess the effectiveness and safety of the femoropopliteal luminor drug-coated balloon angioplasty and against the standard of care which is the non-coated plain old balloon angioplasty.

**Trial Design and Key Results**

Yeah, first of all, we are now looking, we are at the end of our trial after five years. So our primary endpoint was already demonstrated in five years ago, after half a year. And afterwards we are now looking at the follow-up periods, and actually it's quite of interest how long actually such an effect of a one time drug-eluting balloon angioplasty will last over time. And five years, this is really clearly long term results which we are now presenting. And especially in this trial, we are actually looking at all outcome parameters, secondary outcome parameter from patency, target lesion, revascularization, and walking improvement and other endpoints. And the main results we could now show after five years is that there is for this balloon compared to POBA non-coated balloons, that there is no effect on all-cause mortality, meaning the balloons, so no difference in all-cause mortality between the DCB and the POBA. And this means this balloon is safe also on, on long-term considerations. And probably the most important results is that also, well, safe balloons, this is fine, this is what we all expect and what we all want to have, but actually this is also effective and this is something which was quite astonishing in this trial, even after five years, we still see a treatment effect for the DCB as compared to POBA for the primary patency which is still after five years, significant for this time. Meaning the difference is not, is waiting over time from year to year. It was less the difference between luminor and POBA, but still we see a difference around 8% between the treatment groups starting after five years. And at one year it was still was 25%, but still this is statistically significant, and I think this is also something we should be aware of that even on long term, we still have after five years an advantage of using DCB in patients, we have to see it's a one time treatment for those patients who profit from this treatment.

**Challenges**

First of all, the challenge is to have as, and to have not so much of lack of follow-up during a randomised controlled trial. And as you are probably aware of, there was also the discussion starting three years ago about the all-cause mortality of paclitaxel coated balloon and also the luminor is a balloon, which is coated with paclitaxel.

**Luminor and Other Paclitaxel-Coated Balloons**

Yeah, it seems to be, and this is something which we can, well, we have to be careful comparing one randomised controlled trial with another one, especially because of the patient population, which was close in this trial, but from the numbers itself, it seems to be probably one of the most effective balloons products which is on the market. And, but with some, we have to be careful because lesion lengths plays a role, and also what kind of patients were enclosed in the trial. And some might argue that the lesions are relatively short. We are mainly including claudicants which is also the main focus on treating patients with DCB, and therefore, but I think it's quite comparable with other trials and those who also demonstrating five years data probably this balloon is probably the most effective so far. But what is also very important from my point of view, why I'm presenting this at the first at CIRSE in Barcelona, the luminor balloon is as well developed as well as produced in Barcelona itself. So iVascular who is the producer, manufacturer of this balloon is directly located in Barcelona.

**Knowledge Gaps and Next Steps**

Yeah, the knowledge gaps were, we are now really having one of the few trials, RCT trials who are really demonstrating long term data, and I think from not only to show that this balloon is very effective, it's also very important to give more information about the safety. And this is another trial who can demonstrate that paclitaxel coated balloons seems to be also on long run safe so that we have no increased all-cause mortality for the treatment group means for the DCB as compared to POBA. Therefore also the comparison with POBA is an important because it doesn't make sense to have here a head to head analysis, but the next step would be then really to compare head to head the different types of balloons. And this would be probably something which would be feasible for the future to have head to head comparison between different types of balloons.”