LINC TODAY Asia-Pacific
LEIPZIG INTERVENTIONAL COURSE

The official newspaper of LINC Asia-Pacific 2018

Issue 2 Wednesday 14 March 2018

CONTENTS

"Leave nothing behind!" – The new paradigm for SFA treatment?... Main Arena Tuesday 08:00

Tuesday plays host to latest Luminor DCB data

Results from the multicentre, randomised EFFPAC trial were placed centre stage on Tuesday morning at LINC Asia-Pacific, with Ulf Teichgräber, an interventional radiologist from University Hospital Jena, Germany, and Principal Investigator of the study, presenting six-month data using the luminor drug-eluting balloon (DCB; iVascular, Spain).

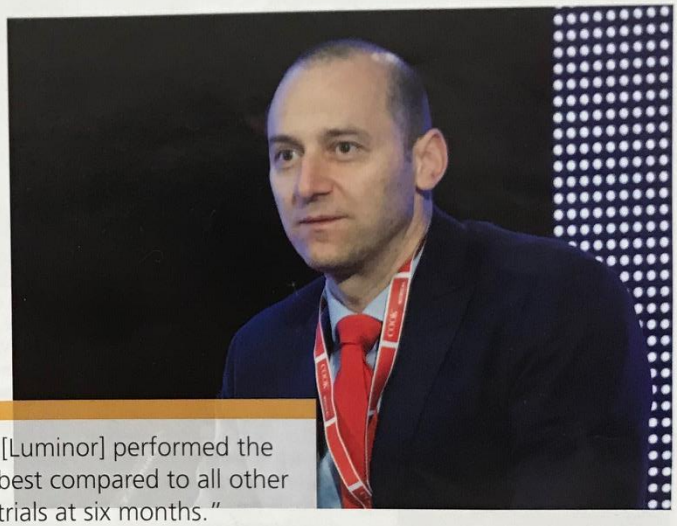
As Professor Teichgräber described, the luminor device is a paclitaxel-coated balloon (3µg/mm2), coated via a proprietary process that ensures a uniform organic ester excipient, in-turn translating to homogeneous drug dose over the whole balloon surface.

EFFPAC is an investigator-initiated, prospective, multicentre, intention-to-treat trial comparing the luminor device with plain old balloon angioplasty (POBA). "The objective is to look at the safety and efficacy of the luminor balloon," said Professor Teichgräber, adding that the study is Core-Lab adjudicated.

"All procedures had a pre-dilatation with POBA, and this was done before randomisation," he said. Non-flow-limiting or flow-limiting dissections were all included, as was bailout stenting, but provisional stenting was not allowed."

The primary efficacy endpoint was late lumen loss (LLL) at six months, with secondary endpoints including freedom from target lesion revascularisation (TLR), patency, and change of ankle-brachial index, Rutherford stage, and quality of life. The primary safety endpoints were minor and major amputation rate for the index limb, and mortality, independent of cause.

In total, 171 patients were enrolled, randomised 1:1 to POBA (n=86) and luminor (n=85). Baseline characteristics were "classic" for peripheral arterial disease (PAD) patients, said Professor Teichgräber, with a mean age of 68 years in both groups, and a male majority (60% luminor, 69.8% POBA). "Most of them were severe claudicants, and the mean lesion length was about 6 cm," continued Professor Teichgräber.



"[Luminor] performed the best compared to all other trials at six months."

Ulf Teichgräber

The total occlusion rate was 20.2% in the luminor arm, versus 25.6% in the POBA arm, and calcification was mild to moderate in both arms. Vessel preparation via pre-dilatation was performed in 100% of luminor cases, and 98.8% of POBA cases. Dissection rates were around 40% in both groups, but the stent rate was relatively low at 15.3% and 18.8% in the luminor and POBA groups, respectively.

The results were "astonishing", commented Professor Teichgräber, with LLL values of 0.14 mm in the luminor group, compared to 1.06 mm in the POBA group (difference [95% CI] = 0.92 mm, p<0.001).

In terms of the improvement of Rutherford class after six months, Professor Teichgräber was very enthusiastic about the results: "This is where it was extremely astonishing," he said. Specifically, there was significantly higher Rutherford improvement in the luminor group compared to POBA (p=0.021). For example, 44.6% of patients in the luminor group saw improvements of three Rutherford stages, versus 27.8% in the POBA group.

The TLR rate was also impressive, at 1.3% for the luminor group versus 17.1% for POBA (p<0.001). "That means we only observed one case of TLR for the luminor," said Professor Teichgräber, adding: "[Luminor] performed the best compared to all other trials at six months."

Looking to patency, the outcomes showed 94.7% versus 75.0% primary patency in the luminor and POBA groups, respectively. Professor Teichgräber added that, once again, this value was the highest among the roster of clinical trials.

Finally, no adverse events were observed for luminor.

Professor Teichgräber offered his conclusions: "The luminor paclitaxel-coated balloon was demonstrated to be clinically, highly effective and safe in inhibiting restenosis compared to POBA. We believe that the innovative coating technology is [important], not only in the superiority in patency, LLL and TLR data, but also in the improvement of Rutherford stage.

"These results allow us, for the first time, to compare this balloon to other RCTs applying paclitaxel-coated technology."

Click here to read the article

Click here to download EFFPAC presentation

EFFPAC-RCT 6 MONTHS OUTCOMES

Multicenter Randomized Controlled Trial to Assess the Effectiveness of Paclitaxel-coated Luminor Balloon Catheter vs. Uncoated Balloon Catheter in the Superficial Femoral and Popliteal Arteries to Prevent Vessel Restenosis or Reocclusion.

	LUMINOR	POBA	p VALUE
Late Lumen Loss (LLL)	0.14mm	1.06mm	<0.001
Freedom from Target Lesion Revascularization (TLR)	98.7%	82.9%	<0.001
Primary Patency (PP)	94.7%	75.0%	<0.001
Rutherford improvement (minimum 1 stage)	85.2%	75.0%	0.021

EFFPAC-RCT 12-months follow-up

Cx Symposium 2018

Tuesday, 24th April. Time: 14.16h (Upper Main Auditorium)

Click here to download EVOLUTION presentation

EVOLUTION 12 MONTHS OUTCOMES

A Prospective, non-randomized, multi center study investigating the Efficacy of the Self-Expanding iVolution nitinol stent for treatment of femoropopliteal lesions.

	IVOLUTION
Freedom from TLR	86.3%
PP	88.0%

iVascular

therapies for living