Two-year outcomes with the LEGFLOW DCB: primary patency maintained in real world patients

Marc Bosiers (St. Blasius Hospital, Dendermonde, Belgium) will give an update at LINC today on the results of the REFLOW[1] study, which investigated the efficacy of the LEGFLOW® drug-coated balloon (DCB) in TASC C and D femoropopliteal lesions.

Primary patency was substantially maintained at two years, Dr Bosiers told *LINC Today*. "The fact that 65.6% of patients were asymptomatic and not experiencing any form of claudication after two years is a very strong clinical endpoint.

"You have to bear in mind that the type of patients who took part in this trial are normally excluded from trials. They are very much real-world patients with complicated TASC C and D, long lesions (of mean length of 216 mm). 67% of them had calcified lesions (Rutherford class 3 or 4) and 45% had occlusions. They were all at high risk of restenosis according to FDA definitions."

Primary patency in the REFLOW study was 65.6% at two years (and 71.1% at one year), while freedom from target lesion revascularisation (TLR) was 70.8%.

Dr Bosiers drew numerical parallels with the findings of the ZILVERPASS study[2], in which a similar population of patients affected by long and complex femoropopliteal lesions were randomised to receive either drug-eluting stent (DES) or bypass surgery. Primary patency after two years was 60% with the Zilver PTX (Cook Medical, IN, USA) versus 59.9% with surgery.

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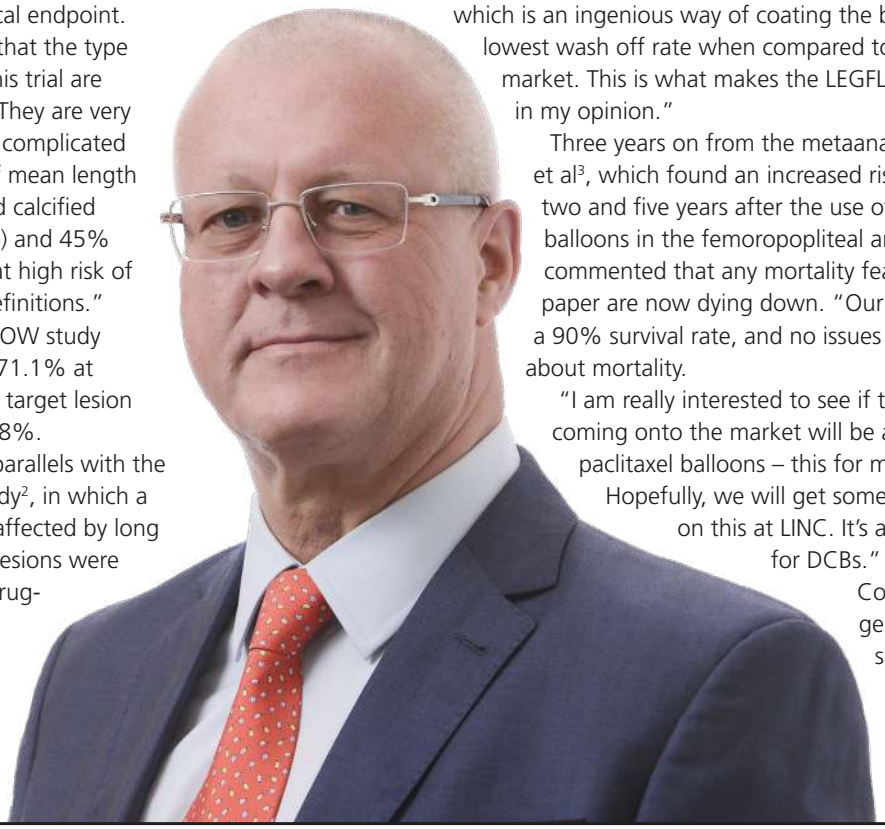

"Freedom from TLR is similar in all three of these arms, but LEGFLOW has the added advantage of leaving nothing behind and not exposing patients to bypass and all of the inconveniences of open surgery.

"After two years of follow up, the survival rate of the 120 patients enrolled in REFLOW was 90%, and none of the deaths that occurred were considered to be related to the device or the procedure. These results confirm the safety of LEGFLOW at long term follow up. This is thanks to the SafePax technology, which is an ingenious way of coating the balloon. It has the lowest wash off rate when compared to other DCBs on the market. This is what makes the LEGFLOW balloon special in my opinion."

Three years on from the metaanalysis by Katsanos et al[3], which found an increased risk of death after two and five years after the use of paclitaxel-coated balloons in the femoropopliteal artery, Dr Bosiers commented that any mortality fears raised by the paper are now dying down. "Our study has reported a 90% survival rate, and no issues have been raised about mortality.

"I am really interested to see if the sirolimus DCBs coming onto the market will be as efficacious as the paclitaxel balloons – this for me is a big question. Hopefully, we will get some first data presented on this at LINC. It's an interesting time for DCBs."

Commenting more generally on the DCB space, he added that more real-world data are needed to reflect

Continued on page 5

Continued from page 4

the types of patients being treated day to day in clinics. "We need more studies like REFLOW to help us work out treatment algorithms to treat our sickest patients.

"I have been involved in clinical research for 25 years. If I look at the patients I treat in my clinic, the types of cohorts included in studies represent only 10–15% of people I see.

"One of the difficulties in getting real world data is that companies are afraid that their results will not be as good as they would be in patients with smaller lesions and studies with strict inclusion and exclusion criteria. These types of studies exclude patients on dialysis, for example, but this is a huge population that develops vascular pathology. This is a really important point for me. Cook have had the guts to do a real world study with the Zilver PTX study – and now Cardionovum with the REFLOW study. We need more companies to do the same."

LEGFLOW OTW is a DCB available in 0,035", 0,018" and 0,014" OTW and RX platforms with 3,0 µg/mm^2 paclitaxel dose, delivered thanks to a specific unique coating technology, SAFEPAX®. The SAFEPAX® non-crystalline coating has the lowest wash-off rate compared to the rest of the DCBs available, providing a safer procedure. This coating matrix is patented by Cardionovum GmbH, a German company with headquarters in Bonn, specializing in manufacturing innovative drug coating technologies, including DCBs and DESs. Cardionovum's R&D Team has been part of the evolution of the drug coating balloon technology for the past 15 years.

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References

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