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INTERVIEW

Latest Updates on the SPORTS Trial and HEAL Registry

An Interview With Thomas Zeller, MD

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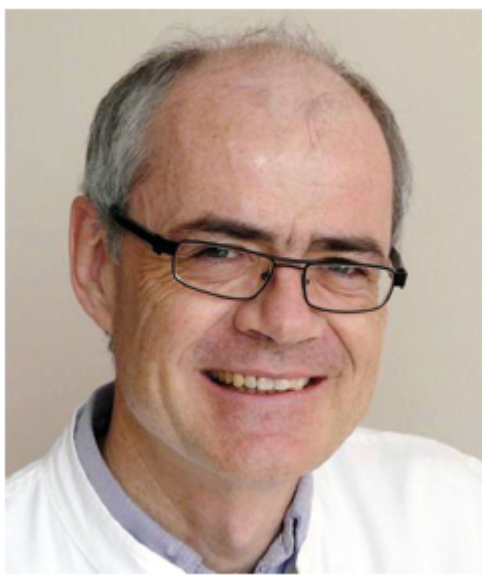
At the 2024 Amputation Prevention Symposium, interventional angiologist Thomas Zeller, MD, from the University Heart Center Freiburg–Krozingen in Bad Krozingen, Germany, discussed 2 of his presentations. The first was on the SPORTS trial, a randomized controlled trial comparing outcomes of a drug-eluting stent (DES; Eluvia, Boston Scientific) vs a bare metal stent (BMS) vs. a drug-coated balloon (DCB; SeQuent Please, B. Braun) in TASC C/D lesions, and the second on the HEAL registry, which collects outcomes data for the treatment of predominantly critical limb ischemia patients implanted with the MicroStent (Micro Medical Solutions) for below-the-knee intervention. Below is an edited transcription of the video Dr. Zeller recorded for us at AMP, which you can watch here.



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The SPORTS study is a randomized controlled study evaluating the performance of DCBs, the SeQuent Please balloon, which is not commercially available here in the US; then the drug-eluting Eluvia stent; and the third study arm was a BMS, and the brand was left to the discretion of the operator. So, study lesions included TASC C and D lesions, meaning minimum lesion lengths had to be 15 cm. At the end, we enrolled 224 patients in total, equally distributed into the 3 arms, roughly more than 70 patients per study arm.

The primary endpoints had been number 1, one superiority endpoint with the hypothesis that the DES outperforms the BMS. The second hypothesis was that the BMS and DCB performance are equal, meaning it was a non-inferiority endpoint.

Basically, at 12 months we had an angiographic follow-up with the primary endpoint, diameter stenosis. Both hypotheses could be confirmed, meaning that we have seen a significantly lower restenosis or diameter restenosis in the DES cohort as compared to BMS and DCB, whereas the outcome for DCB and BMS had been equal.

Both study hypotheses had been confirmed within the study. There was a significantly better outcome in terms of clinical endpoints, meaning freedom from reintervention for the DES arm, which was 94% for the DES arm, 81% for the DCB arm, and 77% for the BMS arm.

Interestingly, this did also translate in a significantly higher proportion of patients being completely free of symptoms at 12 months, meaning qualifying for Rutherford Category 0.

The HEAL study is a single-arm study evaluating the performance of the so-called MicroStent in below-the-knee (BTK) arteries. The MicroStent is a woven stent design similar to the former Wallstent (Boston Scientific) or the Supera stent, offering an excellent compression resistance with a very low outward force.

Low outward force is considered to reduce the vessel wall reaction in terms of reducing near-intimal hyperproliferation. The majority of the more than 200 patients so far included into the trial--it's an ongoing trial--had been patients where the stent had been implanted into the tibial arteries, and just recently a second study arm was implemented, including lesions below the ankle, meaning in the pedal arteries.

So far, 12 lesions below the ankle have been treated within the study protocol. The primary endpoint of the study is the 6-month primary patency rate, evaluated based on duplex ultrasound. Patency is defined as flow without reintervention. The study protocol allows spot stenting within the study; it does not mandate that the entire lesion length has to be covered with the stent. This results in somehow unusual endpoint analysis regarding the patency outcome.

We had been looking into device-related patency and overall patency. Device-related meaning patency inside the stent, and overall patency is covering the entire lesion, which was not standard, which was simply treated with a plain balloon or a DCB. The interesting finding was that it seems to be good to be true, but at 6 months, for the stent-specific patency, it was 100%, meaning there was no reintervention within the stent and no stent occlusion; however, the overall patency was in a range of 80+% at 6 months.

This is an excellent outcome, and it was very similar also for the few cases we did treat so far below the ankle. So it may be that this kind of stent device may become one of the upcoming solutions to treat BTK disease.

What we don't know is If you can really treat a long lesion of 30 cm fully covered with this kind of stent device. The mean standard lesion length within the study was about 5 cm. ■