

The DETOUR procedure: no more need for conventional bypass surgery?

Dainis Krieviņš*

Paul Stradins Clinical University Hospital, Institute of Science, Latvia

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Commentary

The data collected over the course of the DETOUR I clinical trial has been invaluable for studying the evolution of minimally invasive treatments in long, complex lesions of the superficial femoral artery. In the intervening months since this article regarding the first five patients of the DETOUR I clinical trial treated at Paul Stradins Clinical University Hospital was published, an additional 18 limbs under observation at the site have returned for their 2 year follow up, with 100% reporting a Rutherford improvement greater than 3 classes over this time period. Core lab adjudicated patency at this time point is not yet available for all lesions enrolled and treated in the trial; however, it is expected to be released in 2019. Of the five limbs discussed in the April 2018 publication, all remain patent without clinical consequence, and none have exhibited symptoms of venous insufficiency or other deleterious effects on venous health.

DETOUR I trial data have been presented at key milestones at conferences across the globe, demonstrating a similar pattern to what has been observed in the limbs enrolled and studied at Paul Stradins Clinical University Hospital. 12-month follow-up data on the entire enrolled population were presented at the Society for Vascular Surgeons (SVS) this past June, and included a primary, primary assisted, and secondary patency rate of 73.8%, 80%, and 93.8% respectively. Freedom from death was reported in 98.8% of patients enrolled, and 98.8% of limbs enrolled were free from ALI. 100% of limbs enrolled were free from major amputation at 12 months as well [1]. These effectiveness and safety results are impressive when viewed in isolation, however when observed within the context of the extremity, length, and complexity of the lesions enrolled in the DETOUR I trial, they hold an entirely new, and even more promising weight. These medium-term results also provide confidence in the technology's ability to survive in a world where open surgical bypass is considered the gold standard.

The true importance of the continued collection of data in the DETOUR clinical program is building the body of evidence to support the approval of a novel device system and procedure designed to treat complex femoropopliteal occlusive disease. The lesions enrolled in these studies are of a category and complexity that historically, have not received the full benefits

of the advancing field of endovascular therapies, either due to their ineligibility to be enrolled in clinical studies or reduced patency and clinical outcomes. As lesion length is an independent predictor of TLR, these patients are at a higher risk for costly retreatments and reduced patency when treated with the existing armamentarium [2]. In addition to this reduced-term effectiveness, 97.5% of the lesions enrolled in DETOUR I were ≥ 25 cm, long enough to be excluded from most endovascular device trials based on that measurement alone.

The DETOUR procedure is expanding the base of evidence further with the DETOUR II IDE Trial, which began enrollment in December of 2017. Enrolling lesions even longer and more complex than those which were treated in DETOUR I, this pivotal trial aims to provide the necessary data supporting a therapeutic innovation for a historically underserved patient population. The DETOUR II trial will enroll up to 292 limbs with lesions ≥ 15 cm, across up to 40 sites in Latvia, Poland, Germany, and the United States. Paul Stradins Clinical University Hospital continues its interest in and investigation of the DETOUR procedure, enrolling 11 of the patients treated so far in the study. I look forward to further involvement with the DETOUR clinical program and future opportunities to investigate this groundbreaking procedure.

References

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*Correspondence to:

Dainis Krieviņš

Paul Stradins Clinical University Hospital

Institute of Science

Latvia

E-mail : dainis.krievins@stradini.lv