Innovations, latest data, and new techniques in BTK-Interventions Main Arena 1 Tuesday **13:30**

MERLION trial: 24 months outcomes in tibial occlusive disease

SNAPSHOTS @ LINC 2023

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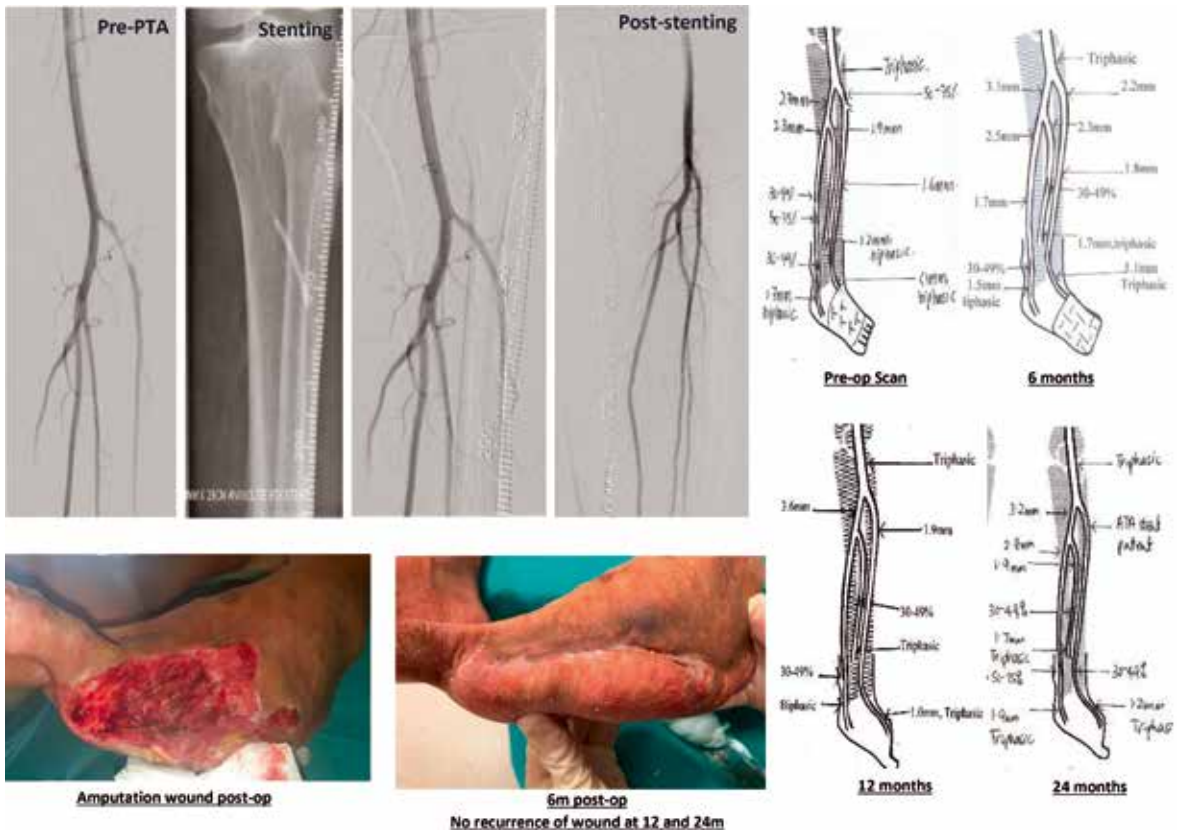

An enrolled MERLION patient showing successful wound healing of a large foot wound that with no recurrence at 12- and 24 months follow-up. The Angiolite drug-eluting stent in the proximal anterior tibial artery remained patent at 24 months, with no target lesion revascularisation performed.

The problem

Diabetic patients with chronic limb-threatening ischaemia (CLTI) usually present with multi-level infra-inguinal peripheral artery disease and tibial arterial occlusions. An endovascular-first revascularisation policy using percutaneous angioplasty is currently preferred to re-establish straight-line blood flow to the foot, necessary for wound healing and limb salvage because of its minimal therapeutic footprint and repeatability. Despite an excellent technical success rate (>90%), tibial angioplasty is plagued by a high incidence of restenosis within the first six months (>70%) because of elastic recoil, development of neointimal hyperplasia (NIH) and vessel wall remodelling. Tibial vessel restenosis and re-occlusion will hinder wound healing, accounts for the high incidence of clinically indicated target lesion revascularisation (TLR) interventions, and increases morbidity in the CLTI setting.

The use of drug-coated balloon (DCB) technology with paclitaxel to inhibit the NIH and restenotic process in the tibial vessels and hence provide more durable patency and sustained blood flow to the foot has been controversial. Although DCB tibial angioplasty with paclitaxel balloons has been associated with lower restenosis and re-occlusion rates compared to conventional balloon angioplasty in several randomised controlled trials, recent meta-analysis data have shown no significant differences in limb salvage, mortality, TLR or amputation-free survival (AFS) between the two modalities, and even may be associated with worse AFS using the DCB platform. The different efficacy results reported between studies may well be down to the excipient coating of the DCB and the potential of distal embolisation or transit loss of drug during transfer to the arterial wall.

Trial insights

The MERLION Trial was a physician-initiated, prospective, observational, non-randomised multi-centre trial, investigating the safety and efficacy of treatment with the Luminor DCB and Angiolite drug-eluting stent (iVascular) in TASC C and D tibial occlusive disease in patients with critical limb ischaemia from a multi-ethnic Asian cohort from Singapore. We report 24 months performance and safety data.

Complication-free survival at one month was the safety endpoint. Immediate technical success, 12-and 24-months primary vessel patency, limb salvage, freedom from TLR and AFS were the efficacy endpoints of interest.

Takeaways

Fifty patients (64% male; mean age 66 years) were included. The majority were Rutherford 5 severity (41/50; 82%). Co-morbidities included diabetes mellitus (47/50; 94.0%) and end-stage renal failure (25/50; 50.0%); 66 atherosclerotic lesions were treated (47 de novo and 19 restenotic; 39% TASC D). Mean lesion length treated was 14 ± 9.5 cm. There was 100% technical success. There were 3/66 (4.5%) bailout stents for severe flow-limiting dissections.

The safety profile was excellent (no deaths within 30 days), six-month AFS was 86%, 12-month AFS was 74%, and 24-month AFS was 55%. What's more, freedom from TLR was 91%, 82% and 78% at 6-, 12- and 24 months, respectively. Wound closure was achieved in 66% of subjects, and 60% improvement by at least 1 Rutherford category at 12 months. This improved to 83% and 85%, respectively, at two years.

The iVascular Luminor DCB is safe and efficacious in treating highly complex infra-popliteal atherosclerotic lesions in the medium term in an otherwise challenging frail population of CLTI patients, with a high incidence of diabetes and end-stage renal failure, reflective of everyday lower limb revascularisation practice in Singapore.