

Utility of Drug-Eluting Balloons in the Treatment of Restenosis after Deep Venous Arterialization

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Introduction

Deep Venous Arterialisation (DVA) is a viable option for patients with “end stage”, no option critical limb Ischaemia. This can be done via open Deep Venous Bypass Surgery or more recently a completely percutaneous approach. The development of AVFs and arterialisation of the veins of the foot seem to hold promise¹⁻⁴.

In attempts to improve the venous runoff after DVA, endovascular approaches have been used to balloon and disrupt venous valves as well improve runoff by balloon assisted maturation. Certainly one of the consequences has been restenosis in these veins.

Drug-eluting balloons (DEBs) have a proven record in the treatment of short lesions in the SFA but remains controversial in the vessels below the knee as well as in the veins. There is some early evidence that it is useful to delay restenosis in AVFs created for dialysis access, via the inhibition of smooth muscle proliferation and neointimal hyperplasia⁵. Lesions in the AVFs treated with POBA seem to have poorer patency rates compared to those treated with DEBs⁶⁻⁸. More recently, Medtronic received the CE Mark for its IN.PACT DEBs in the maintenance of hemodialysis access.

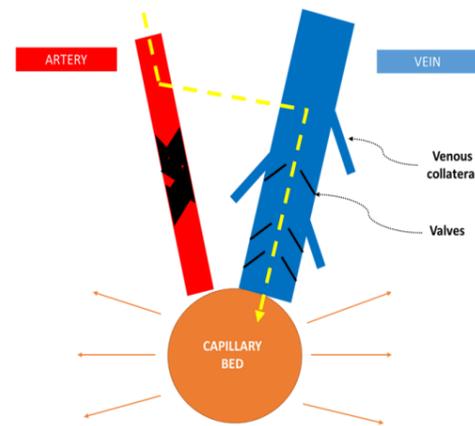


Figure 1: Concept of Deep Venous Arterialization

Aim

To review the safety and efficacy of the usage of DEBs in the treatment of restenosis post-DVA.

Methodology

We report a total 7 cases (1 open hybrid DVA, 6 Percutaneous DVA/LimFlow Procedure) in which DEBs were utilised to treat stenosis in the arterialised veins in the foot. This is a retrospective review of prospectively observed cases. This proof-of-concept study was carried out in Changi General Hospital in Singapore.

Patient demographics, angiographic details of lesions, as well as wound characteristics were recorded. More pertinently, the safety, angiographic outcomes, and types of DEBs used were also collated.

Clinical and ultrasound surveillance were performed at select intervals.

Results

A total of 7 patients who underwent DVA were included in the study, 6 of whom developed clinically significant restenosis requiring intervention. 1 patient had a DEB-assisted maturation performed during the index DVA procedure. A total of 10 interventions with DEBs were performed. All patients were treated with either the IN.PACT Pacific DEB (Medtronic) or the Lutonix DEB (Bard), both paclitaxel-coated balloons. A total of 15 IN.PACT and 6 Lutonix balloons were utilized.

All the patients had Critical Limb Ischaemia (CLI), with 5 out of 7 having Rutherford 6 CLI. They were deemed to have CLI not amenable to conventional arterial bypass or conventional angioplasty due to poor target vessels or absence of plantar arch (aka “desert foot”). They all also had multiple co-morbidities including diabetes and ESRF in half the patients.

The details of the angiographic outcomes were analysed. 6 of 7 target vessels were segments of veins that had been previously undergone arterialisation. The mean size of arterialised vein was 3.5mm. Most common size of balloon used was 4mm. A significant number of lesions were complete occlusions, some of which were acute. Also of note are the significant number of ISRs (50%) and the distal location of these vessels. The treated vein was the Lateral Plantar Vein in 80%, Venous Arch in 50%, Dorsalis Pedis Vein in 19% and the Anterior Tibial Vein in 6% of the cases.

The mean time to loss of primary patency post-DVA was 109 days. Indications were restenosis in 50% and complete occlusion in 40% (for which supplementary Rotarex thrombectomy was concomitantly performed). Of patients with multiple DEB interventions, the average time between interventions was 155 days. As of 16/1/16, the longest DEB-assisted patency was 630 days, with an average of 336 days of DEB-assisted patency. The 6 month limb salvage was 86% and 80% of the wounds had healed by 6 months in the entire cohort of patients who underwent percutaneous DVA. There was no evidence of any adverse effect of embolization of the Paclitaxel on the wound healing.

Conclusion

Deep Venous Arterialization is an emerging technique to treat Critical Limb Ischemia. DEBs have been proven in the treatment of SFA de-novo and ISR lesions, and are emerging as a viable option for maintenance of AVF patency. We report the successful utility of DEBs in the treatment of restenosis in patients who have undergone this procedure.

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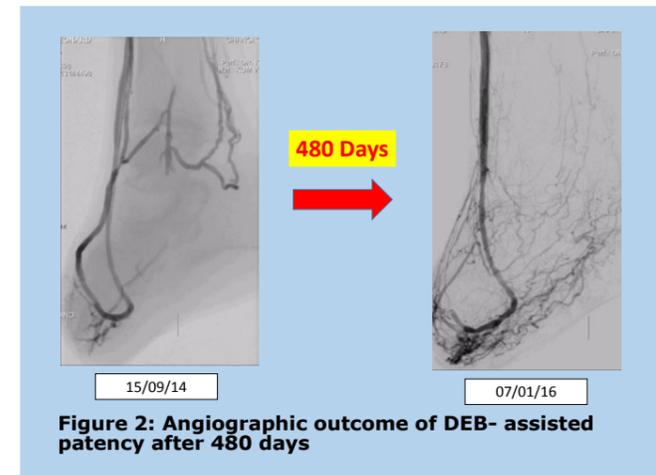


Figure 2: Angiographic outcome of DEB-assisted patency after 480 days

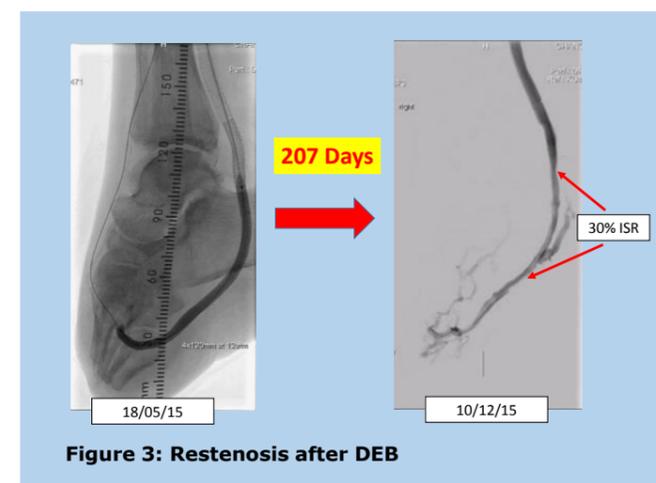


Figure 3: Restenosis after DEB