

Early and Eighteen Month Clinical Outcomes of First UK Case of Percutaneous Deep Vein Arterialisation (pDVA) to Treat “No Option” Chronic Limb-Threatening Ischemia Using the Limflow System

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Abstract

Background: Chronic limb-threatening ischaemia (CLTI) in cases where there are no further standard treatment options for limb salvage represents the most advanced stage of peripheral arterial disease. This case represents the first UK use of the LimFlow System to perform percutaneous deep vein arterialisation (pDVA) in a “no option” CLTI patient, with outcomes out to 18 months post-procedure.

Case Presentation: We present the case of a 78 year old male diabetic patient with a history of contralateral below knee amputation who presented with ischaemic rest pain and dry gangrene involving his left heel and first and second toes. Following review by the lower limb multi-disciplinary team at our institution, the patient was deemed to have no surgical or endovascular treatment options, apart from major amputation, as there was no viable target for angioplasty or bypass. He was therefore referred as a candidate for percutaneous deep vein arterialisation (pDVA) with the LimFlow System (LimFlow SA, France). After screening of the patient according to the indications for use, the pDVA procedure was successfully performed resulting in complete resolution of ischaemic rest pain immediately following the procedure, and adequate revascularisation of the foot. The subject went on to have minor amputation of the first, second and third toes 2 months post initial procedure with further secondary angioplasty procedures to optimise the flow throughout the arterialised circuit up to 4 months after the initial procedure. He underwent elective completion transmetatarsal amputation at 13 months post index procedure. The surgical wounds post minor amputation and the heel wound showed continued healing progress, especially after secondary optimisation of the pDVA outflow, with tissue epithelialisation by 6 months and complete healing by 18 months post index procedure.

Conclusions: This case report demonstrates the clinical outcomes of a technically-successful LimFlow pDVA including both limb salvage and wound healing at 18 months.

Background:

Chronic limb-threatening ischaemia (CLTI) originates in occlusive arterial disease and is characterised by ischaemic rest pain and foot wounds including ulcers or gangrene classified as Rutherford class 4–6. On its own, CLTI has a prognosis of 20% mortality at 6 months and over 50% at five years^{1,2,3}. Amongst these patients, 20% have no further options for surgical or endovascular treatment due to the lack of suitable distal target vessel or due to other co-morbidities⁴. These so called “no-option” CLTI patients have an even worse prognosis of 40% major amputation and 20% mortality at 6 months⁵. Percutaneous deep vein arterialisation (pDVA) presents an opportunity first and foremost for limb salvage and has demonstrated amputation free survival (AFS) of 84% and 71% at 6 and 12-months respectively where pDVA has been performed using the dedicated LimFlow System. Further to avoiding amputation, the re-establishment of blood flow to the foot after pDVA ultimately allows complete wound healing of 37% and 68% at 6 and 12-months respectively in patients treated with this procedure⁶.

Case Report:

A 78-year old male patient with recent contralateral right below-the-knee amputation initially presented in July 2019 with ischaemic rest pain and dry gangrene involving his left heel and his first and second toes. His comorbidities included type II diabetes, hypertension, previous stroke and hypercholesterolaemia. Duplex ultrasound showed a focal stenotic lesion in the distal SFA and heavily calcific occlusive tibial disease. He was classified as Rutherford category 5 with a Society for Vascular Surgery Wifl “wound, ischemia and foot infection” score of 2-3-0, which meant he was at high risk of major amputation within the year. The patient initially underwent balloon angioplasty of the SFA but angiography revealed poor outflow to the foot with no suitable target for distal angioplasty or bypass (Fig. 1A). The lower limb multidisciplinary team at our institution reviewed the case and agreed to proceed with pDVA as the only possible treatment apart from major amputation.

The patient underwent successful screening for pDVA, according to the indications for use, that included duplex assessment of the tibial and plantar deep veins to confirm appropriate vessel anatomy for arterialisation. The pDVA procedure was performed in August 2019 as the first use of the LimFlow System in the United Kingdom. Under ultrasound guidance, arterial access was performed antegrade in the left CFA and venous access was performed in the lateral plantar vein. Using the LimFlow arterial and venous catheters, an arterial-venous communication was created at the level of the proximal posterior tibial artery into a posterior tibial vein. The target posterior tibial and lateral plantar veins were then treated with the LimFlow antegrade (push) vavulotome to render the valves incompetent which was confirmed with balloon dilatation. Finally, the LimFlow self-expanding PTFE-covered stents were deployed in the posterior tibial vein distally from the ankle level to the crossing location where a conical stentgraft was deployed to secure the fistula and optimise flow transition from the artery into the vein. The completed pDVA circuit successfully established blood-flow to the foot (Fig. 1B) and post-procedure ultrasound demonstrated a satisfactory volume flow of 250cc/min in the arterialised lateral plantar vein. The case took just under three hours from the time of initial access until final access site closure to perform.

The procedure was technically successful with no perioperative complications. The patient experienced an almost complete resolution of ischaemic rest pain following the procedure and did not experience any adverse events in the first 60 days following the procedure. The patient underwent close duplex ultrasound surveillance to monitor flow into the affected area. At ten weeks following the procedure, the patient presented with diabetic foot sepsis and underwent hallux, second and third toe amputation and foot debridement. At the same time, angioplasty was performed to treat the narrowing of the inflow and outflow tracts of the stent grafts at the level of the origin of the posterior tibial artery as well as in the lateral plantar vein. No signs of in-stent stenosis were observed at the time of inflow and outflow treatment. Further angioplasty was performed at 3 months with the implantation of a Supera stent into the lateral plantar vein distal to the LimFlow stent to enhance the flow in the venous arch, and to coil embolise collateral veins in order to focalise blood flow to the distal foot. At four months, the patient underwent a final maintenance angioplasty where the outflow pedal venous arch was treated with balloon angioplasty to further aide circulation to the area of the toe amputation (Fig. 1D). The heel ulcer and minor amputation wounds showed continued improvement post-pDVA with tissue granulation after

debridement at 2 months and complete epithelialisation by 12 months (Fig. 2). Ischaemic rest pain resolved almost completely after the index procedure and the patient did not report any pain by 6 months and onward. Due to bone protrusion from the wound, a completion transmetatarsal amputation was performed at 13 months.

Conclusions:

In conclusion, this first UK case of the LimFlow System in treating a no-option CLTI patient with pDVA demonstrates the feasibility of this treatment in terms of safety and effectiveness, not only acutely with the creation of blood flow to the extremity as evidenced by a resolution of ischaemic rest pain, but also with respect to the longer term clinical outcomes of limb preservation and wound healing.

Abbreviations

CLTI : Chronic limb-threatening ischaemia

pDVA: Percutaneous deep vein arterialisation

Declarations

Ethics approval and consent to participate

The pVDA procedure received approval from the new devices and new techniques committee and the ethics committee of our Trust. Written informed consent was obtained from the patient for all the procedures described in this study

Consent for publication

Written informed consent was obtained from the patient for publication of this case report and any accompanying images

Availability of data and materials

Not applicable

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

SL wrote the paper, assisted in the index surgery, and performed follow-up interventional procedures

KS performed the index surgery , read, modified and approved the final manuscript.

RGMcW read, modified and approved the final manuscript

Aknowledgments

Not Applicable

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Figures

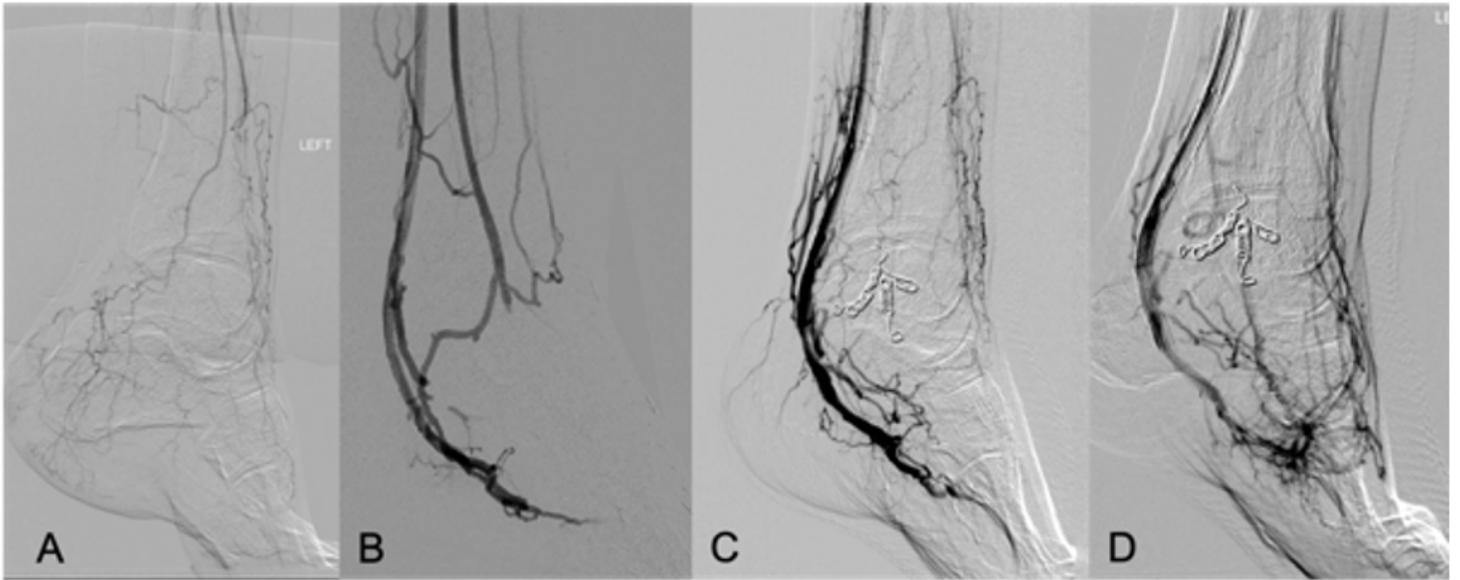


Figure 1

A) Baseline angiogram, B) post index pDVA, C) post collateral vein embolization D) post final outflow optimisation with angioplasty of the pedal venous arch



Figure 2

Progression of wound healing baseline to 12 months post pDVA



Figure 3

Most recent images of the foot, 18 months post pDVA