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Case Study

Percutaneous distal venous arterialisation (pDVA) in a patient with no-option chronic limb threatening ischaemia (CLTI)

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Key Learning Points

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The This case report clearly illustrates the indications, technical details, and outcomes of a novel and unique procedure in which the venous bed of the lower limb is used as an alternative conduit for perfusion in patients with end stage critical limb ischaemia. Although this procedure is in its infancy, and we are still refining the technique and patient selection, the early outcomes are very encouraging with a 50% limb salvage and wound healing rate.

Introduction

Peripheral arterial disease (PAD) affects around 200 million people worldwide[1]. Patients with PAD are at risk of developing chronic limb threatening ischaemia (CLTI) and tissue loss as the disease progresses. With major amputation occurring in around 30% of patients[2], CLTI is a condition associated with significant morbidity. Management is often complex and resource intensive as patients have significantly impaired wound healing. Studies show that with no intervention only 20% of patients achieve adequate wound healing at 1 year[3].

Avoiding amputation in CLTI patients is sometimes not achievable as revascularisation attempts fail due to severe calcification and/or absence of target distal vessels. This pattern of small artery disease seen in PAD can be described as a failure of distribution[4] and is exceedingly difficult to treat. 'Desert foot' describes the most severe form of PAD in which there are no patent major vessels identifiable on angiography. Patients with desert foot are often termed 'no-option' due to a lack of viable target vessels for endovascular therapy or bypass.

However, one potential new prospect to return perfusion to no-option CLTI patients is percutaneous distal venous arterialisation (pDVA). This technique uses the venous system as a conduit for arterial blood[5-7]. This approach is viable as the venous system often remains disease free even in patients with severe PAD. The goal of pDVA is to improve perfusion and wound healing as retrograde flow through distal veins feeds capillary beds with arterial blood. pDVA has shown to be a promising option for revascularising the lower limb following both first-in-man studies and feasibility trials[8,9].

This case study presents the management and 18 month follow-up of a patient with no-option chronic limb threatening ischaemia. The patient elected to undergo distal venous arterialisation as an experimental procedure to restore perfusion to his compromised limb.

Case History

82-year-old male known to vascular surgery services with long-standing PAD and CLTI of the left leg affecting the distal metatarsals and toes. The patient has a background of right below-knee-amputation due to PAD, diabetes, chronic obstructive pulmonary disease, atrial fibrillation, and antiphospholipid syndrome. Assessment showed dry gangrene of the left foot and pain at rest. At the time of presentation the patient was anticoagulated with warfarin and in full-time care.

Management

Pre-intervention angiography of the left leg revealed patent superficial femoral and popliteal arteries. Peroneal and anterior tibial arteries were patent at the level of the ankle. The posterior tibial artery was occluded proximally, and a severe lack of perfusion in the foot was noted, with no major arteries identifiable. These findings were consistent with severe distal vascular disease, a classic 'desert foot' presentation [Fig. 1a].

During his stay in hospital the patient suffered progressive necrosis of the toes despite medical management with vasodilators. Two attempts at traditional angioplasty were attempted to return perfusion to the foot. In both cases these did not achieve optimal outcomes due to the paucity of patent arteries in the foot. It was felt that due to the viability of the foot being threatened and the lack of alternative treatment options available this patient would be an ideal candidate for pDVA. Upon discussion the patient agreed to undergo pDVA as an experimental procedure in full knowledge that trans-metatarsal amputation would be likely even with optimal endovascular outcomes.

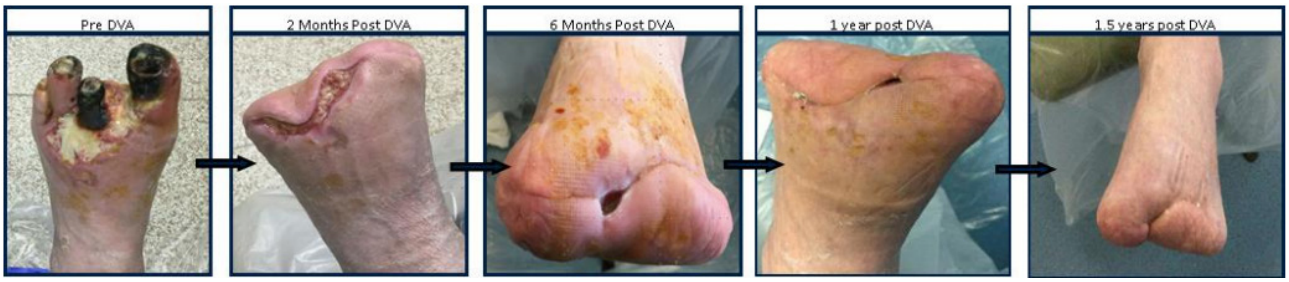

Figure 1: Picture timeline of wound healing through to 1.5 years

Procedure

Posterior tibial artery and vein were cannulated, and an Outback re-entry device was used to puncture from the proximal artery into the vein. Covered stents were then placed across the fistula tract (Papyrus Biotronik 4x26mm, Viabahn 5x100mm). Proximal valves rendered incompetent with balloon venoplasty (standard 6x100mm, Angiosculpt 6x100mm balloons).

Outcomes

Angiography two weeks post procedure showed outflow shunting away from the target site through several collateral veins. This was consistent with a lack of improve in the patient's overall clinical picture. As a result, these competing collateral veins were occluded with covered stents in a second procedure (Viabahn 6x50mm and 8x50mm). Good flow around the plantar arch was found on imaging post procedure [Fig 1b]. At 2-month follow up granulation tissue could be seen at wound edges. Examination showed a warm and perfused midfoot with good doppler signal from the arterialised vein. Healing continued with marked improvement seen at the 6-month follow up. The wound was deemed fully healed at the 1-year appointment, with further improvement seen at 18 months [Fig 2].

Discussion

This report details the case of an 82-year-old male with no-option CTLI who elected to undergo pDVA following failure of traditional angioplasty to successfully return perfusion to his threatened limb. In this patient pDVA has proven itself to be a viable intervention for returning perfusion to a compromised limb that lacks suitable end arterial targets. In discussion the findings of current pDVA studies will be explored and used to highlight a pertinent point brought to the forefront by this case.

The viability of pDVA as a therapeutic option is being assessed in various trials worldwide, including the PROMISE I[9] and ALPS studies[3]. The PROMISE I trial out of Michigan, USA investigated the efficacy of pDVA in 10 patients. Reported outcomes include amputation free survival, technical success of the procedure, reintervention rates and primary patency. Early results are encouraging with the PROMISE I trails finding 6 month amputation free survival in all patients. Reintervention rates stand at 30%, and by 6 months 3 patients were found to have fully healed wounds. The multicentre ALPS (Alkmaar, Leipzig, Paris, and Singapore) study represents the largest cohort study, with 32 Rutherford Class V and VI patients enrolled. Mid-term reports found that at 6, 12, and 24 months, estimates were 83.9%, 71.0%, and 67.2% for amputation free survival respectively.

Despite encouraging early reports, the number of pDVA studies is small and those that are currently underway are limited by cohort size. To account for this, meta-analysis of several pDVA studies has been carried out[10]. Promisingly, this analysis found limb salvage rates of around 75% across all studies. There remains limited literature into the rate and severity of complications in patients that have undergone pDVA. Complications of pDVA include prolonged hospitalisation, venous gangrene, wound infection, failure of procedure and excessive foot oedema. In the future larger studies and analyses will be needed to further evaluate the clinical value of pDVA at scale.

Furthermore, it is important to note that these existing studies employ the LimFlow stent graft system to achieve distal arterialisation of venous targets. Purpose built pDVA systems such as LimFlow are currently in limited availability in the NHS. Our case differentiates itself in that standard endovascular equipment was used to achieve successful pDVA. As a result, approaches utilising alternative, readily available systems to achieve arteriovenous fistula creation may well become commonplace until such devices

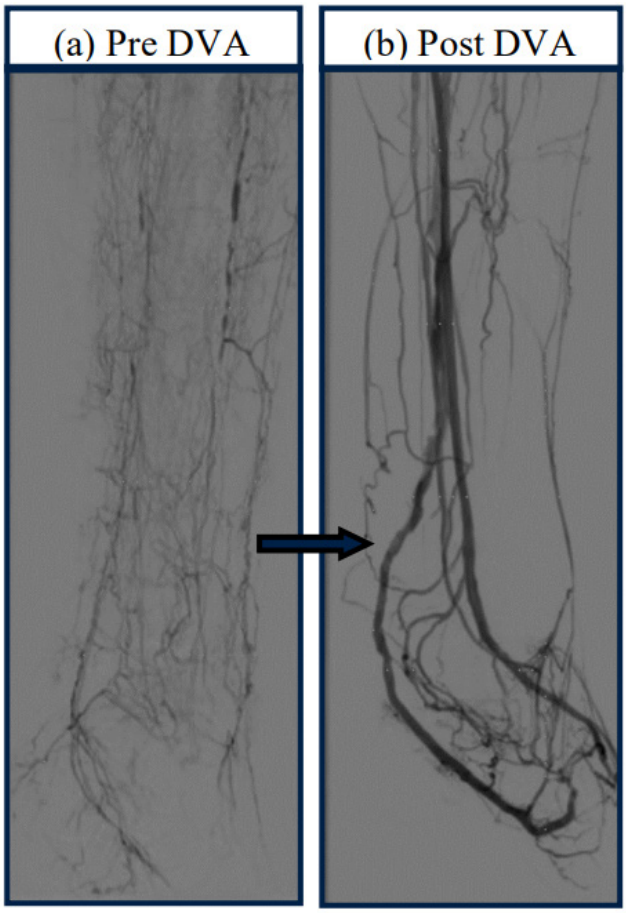

Figure 2: (a) Pre-pDVA (b) Post-pDVA and collateral occlusion

become more widely accessible.

It appears that the efficacy of pDVA is emerging in several study groups. However, the cost-effectiveness of pDVA vs conservative management remains to be determined in literature. This presents a sizeable challenge to the mainstream acceptance of this treatment modality. Encouragingly standard endovascular revascularisation has proven to be cost effective when compared to conservative management. A 2019 observational study from Peters et al compared the differences in cost associated with conservative vs endovascular management of CLTI patients[11]. In their conclusion endovascular revascularisation was found to be cost effective when compared to conservative measures. Thus, comparing outcomes in no-option CLTI patients that have undergone pDVA vs their conservative counterparts presents an avenue for further research.

Conclusion

For no-option CLTI patients pDVA is emerging as a viable and potentially limb saving procedure. Early reports from studies indicate that amputation free survival is higher in pDVA patients when compared to non-pDVA patients[12]. This case report illustrates a successful outcome following pDVA using standard endovascular equipment, distinguishing this report from others utilising the purpose built LimFlow device. The cost effectiveness and true efficacy of pDVA using non-specialised equipment remains to be seen and further studies into this area are needed in the future.

Conflicts of interest

None.

Funding

None.

Consent

The patient has consented to the publication of this case study.

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