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Pedal artery revascularisation: Is it ready for prime time?

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Srini Tummala

Reviewing the available evidence for below-the-ankle interventions in the treatment of critical limb-threatening ischaemia (CLTI), Srini Tummala proposes that pedal artery intervention "should be an integral part of the armamentarium" when physicians are faced with patients with both below-the-knee and below-the-ankle disease. Although he calls for more data to consolidate this view, he highlights how the existing literature demonstrates a higher rate of wound healing and a shorter time to wound healing when additional pedal artery revascularisation is performed with below-the-knee interventions.

CLTI is the most severe form of peripheral arterial disease (PAD), and is classified by ischaemic rest pain, ulcers, or gangrene in the lower extremities attributed to objectively proven arterial stenoocclusive disease. Diabetes is a major risk factor, resulting in atherosclerosis occurring at a younger age and affecting mostly the infrapopliteal arteries.¹ Revascularisation with bypass or endovascular therapy (EVT) is an important treatment to avoid or minimise amputation based on the latest guidelines.^{2–4} Surgical bypass, however, is not always an option, as many CLTI patients with infrapopliteal disease may not be surgical candidates due to frailty, co-morbidities, advanced age, or poor distal bypass targets. ^{2–4} EVT for infrapopliteal disease has become commonplace, and studies have shown a comparable limb salvage rate to surgery, but there is still an apparent discrepancy between limb salvage rate and the rate of wound healing.⁵⁻¹⁰ Delayed wound healing has increased morbidity, lowers quality of life, and also increases medical costs even if limb loss is successfully prevented.^{6,9,10} Clinical trials have reported that the presence of below-the-ankle disease results in worse wound healing, thus pedal artery revascularisation is of paramount importance to achieve complete wound healing.^{7,10}

About a decade ago, the safety and effectiveness of below-the-ankle angioplasty was unclear, and it was uncertain whether additional below-the-ankle angioplasty after below-the-knee (BTK) angioplasty improved clinical outcomes.¹¹ Since then, new tools have been introduced, and many advanced techniques have been described for pedal artery revascularisation, but the lack of randomised

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controlled trial data and long-term results, coupled with the potential risks (including dissection, spasm, rupture, and thrombosis), have limited widespread adoption of these interventions.^{12–18}

In 2009, Manzi and colleagues showed that below-the-ankle interventions in CLTI patients were not only feasible, but safe, and that they appeared to provide positive clinical results at both short and mid-term follow-up. In their analysis, they consecutively treated a total of 1,331 patients with BTK disease of which 135 (10.1%) underwent below-the-ankle revascularisation with pedal-plantar loop technique in order to recanalise the pedal arteries. Technical success for the pedal-plantar loop technique was 85%. Clinical improvement and functional status was obtained and maintained after an average of 12 months, with a significant improvement of transcutaneous oxygen tension (TcPO2) after 15 days. TcP02 was 59+/-16mmHg in the below-the-ankle intervention group when it was successful versus 42+/-12mmHg in patients where patency was achieved in two BTK vessels down to the ankle level with partial out-flow in the foot (p<0.001).¹⁸

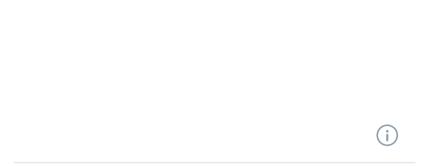
Shortly thereafter, Kawarada et al described a pedal arch classification system and demonstrated that the status of the pedal arch was an independent predictor of wound healing. Based on data from the RENDEZVOUS registry, Nakama *et al* demonstrated that the speed and extent of wound healing was improved with below-the-ankle angioplasty.^{19,20} This registry was multicentre, and included 317 CLTI patients presenting with infrapopliteal arterial disease who underwent EVT at five experienced cardiovascular centers in Japan. Nakama et al retrospectively reviewed 257 of these CLTI patients who presented with *de novo* infrapopliteal and pedal artery disease. Patients were then divided into two groups according to whether pedal artery angioplasty (PAA) was performed (n=140) or not (n=117). The rate of wound healing was higher in the PAA group (57.5% vs. 37.3%, p=0.003), and the time to wound healing shorter (211 days vs. 365 days; p=0.008).

More recently, in 2019, Huizing et al published a systematic review and meta-analysis of below-theankle angioplasty in CLTI patients. Their review included ten articles which reported a total of 478 patients with below-the-ankle angioplasty performed in 524 legs. The pooled 12-month limb salvage rate was 92%, and there was no statistically significant difference found in limb salvage when additional below-the-ankle angioplasty was compared to BTK angioplasty only. The pooled 12-month amputation-free survival was 78% and no statistically significant difference was found in amputationfree survival when additional below-the-ankle angioplasty was compared to BTK angioplasty only. This systematic review and meta-analysis showed that additional below-the-ankle angioplasty is a safe and feasible procedure, with a 92% pooled proportion of limb salvage at 12 months. Although no significant difference was found in limb salvage rates or amputation-free survival rates when BTK angioplasty only was compared to BTK angioplasty plus additional below-the-ankle angioplasty, the wound healing rates were better in the additional below-the-ankle angioplasty group. Specifically, Nakama et al in 2016 and 2017 showed wound healing rates of 93% versus 60%, and 59% versus 38%, respectively, favouring additional below-the-ankle angioplasty. Finally, with more severe pedal artery disease, wound healing results were better in the additional below-the-ankle angioplasty group compared to the BTK angioplasty only group.¹¹

In conclusion, the currently available evidence suggests that pedal artery revascularisation is a safe and feasible procedure. Data also suggest no significant difference in limb salvage rates or amputationfree survival when additional below-the-ankle angioplasty was compared to BTK angioplasty only. However, wound healing rates are higher and time to wound healing shorter when patients undergo additional pedal artery revascularisation. This begs the question—is pedal artery revascularisation ready for prime time? While high-quality research is most certainly needed to clarify the benefits, available evidence suggests pedal artery intervention should be an integral part of the armamentarium to treat CLTI patients when there is BTK and co-existing below-the-ankle disease in cases of wound healing and limb salvage.

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