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A Prospective Study to Evaluate Complete Wound Healing and Limb Salvage Rates After Angiosome Targeted Infrapopliteal Balloon Angioplasty in Patients with Critical Limb Ischaemia

Ahmed Elbadawy *, **Haitham Ali, Mahmoud Saleh, Ayman Hasaballah**

Vascular and Endovascular Surgery Department, Assiut University Hospital, Assiut, Egypt

WHAT THIS PAPER ADDS

This prospective study of angiosome targeted balloon angioplasty of infrapopliteal occlusive lesions demonstrates the importance of a direct revascularisation first strategy whenever feasible as it provides a better 12 month complete wound healing rate. However, getting flow to any of three leg vessels offers similar rates of limb salvage or amputation free survival.

Objective/Background: To evaluate complete wound healing and limb salvage rates in patients with critical limb ischaemia (CLI) with concurrent foot ulceration/gangrene who underwent angiosome targeted infrapopliteal balloon angioplasty.

Methods: This was a prospective observational study. In total, 212 patients who underwent successful infrapopliteal balloon angioplasty to assist wound healing and achieve limb salvage were included from June 2014 to March 2016. Propensity score matching was developed to compare complete wound healing, 1 year amputation free survival (AFS), and limb salvage rates between the two study groups (direct revascularisation [DR] and indirect revascularisation [IR]).

Results: Direct flow to the foot wounds based on the angiosome principle was achieved in 117 legs (55.2%) versus 95 legs (44.8%) that represented the IR group. Seventy-three matched pairs were obtained to minimise intergroup differences in baseline characteristics. Twelve months after angioplasty, the complete wound healing rates were 80.8% and 63.0% ($p = .02$), AFS rates were 72.6% and 61.6% ($p = .164$), and limb salvage rates were 90.4% and 82.2% ($p = .148$) in the DR and IR groups, respectively.

Conclusion: This study suggests that the complete wound healing rate is better when the target foot lesion receives direct perfusion following the angiosome concept, whereas limb salvage and AFS rates were not significantly different among the DR and IR groups.

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INTRODUCTION

Non-healing wounds and threatened limb salvage in patients with critical limb ischaemia are ongoing concerns for vascular physicians trying to avoid major limb amputation. Despite successful revascularisation, a number of failures to achieve limb salvage have suggested that clinical success of bypass surgery or angioplasty may depend on the target of revascularisation.[1]

Anatomical description of angiosomes began in the 1970s in plastic surgery as a means of optimising tissue transfer. Taylor and Palmer first described the angiosome concept as a block of tissue comprising skin, subcutaneous tissue, fascia, muscle, and bone, supplied by a specific artery and drained by a specific vein.[2]

Subsequently, Attinger *et al.* adapted the idea of angiosomes to peripheral revascularisation in patients with CLI.[3] They described six angiosomes of the foot and the lower leg that are fed by the three tibial arteries: the anterior tibial artery (ATA), the posterior tibial artery (PTA), and the peroneal artery (PA). Depending on the location of an ulcer or gangrene there are two revascularisation possibilities: *direct* revascularisation (DR), aiming to treat the vessel that feeds the ulcer bearing angiosome; and *indirect* revascularisation (IR) meaning treatment to one of the tibial vessels not feeding the affected angiosome directly.[3]

The argument remains whether establishing *direct* arterial flow to an ischaemic region will provide the best chance for wound healing and limb salvage or getting flow to any of the three leg arteries should be adequate for the presence of sufficient collaterals.[4]

* Corresponding author. Western Staff Residence, Building M – Flat 1, Assiut University, Assiut 71515, Egypt.

E-mail address: ahmedhassan.bakr@gmail.com (Ahmed Elbadawy).

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The aim of the current study was to evaluate *complete* wound healing, amputation free survival (AFS) and limb salvage rates in patients with CLI with concurrent foot ulceration/gangrene who underwent angiosome targeted infrapopliteal balloon angioplasty.

METHODS

A prospective observational study design with patient enrolment ran between June 2014 and March 2016, and 1 year follow-up ended in March 2017. The Institutional Review Board approved the study protocol developed in accordance with the Declaration of Helsinki. All patients gave written informed consent prior to revascularisation.

Patient selection

Potential candidates were all consecutive patients admitted to the vascular and endovascular surgery department of a tertiary referral hospital during the study period and presenting with Rutherford stage 5 and 6 CLI (ischaemic ulcer or gangrene, either dry or wet)[5] due to infrapopliteal occlusive lesions, without significant superficial femoral or inflow arterial disease. Included patients were those who underwent successful percutaneous balloon angioplasty of one of the leg vessels to assist wound healing and achieve limb salvage. Exclusion criteria were: (i) Rutherford category 4; (ii) failed wire crossing and revascularisation; (iii) successful revascularisation of more than one tibial vessel, resulting in situations of a *combined* DR and IR or an IR with two crural vessels re-opened, to avoid their confounding impact on study outcomes.

Patient assessment

Patient risk factors, including diabetes mellitus, hypertension, dyslipidemia, renal impairment, smoking, and history of ischaemic heart disease, were reported. Pre-operative pulse examination and ankle brachial index (ABI) measurement were performed for all cases. In the case of non-compressible vessels, digital pressure was assessed. The infrapopliteal arteries were routinely evaluated using duplex ultrasound to localise the arterial lesion and assess its severity through velocity criteria and waveform changes.

A foot ulcer was defined as a full thickness skin defect distal to malleolar level present for at least 2 weeks. Diabetic patients with borderline ankle/toe pressures and presenting with infected wounds underwent surgical debridement to remove devitalised and infected tissue. A guarded brief period of conservative best wound management before the intervention was followed. All patients received appropriate off loading, antibiotic therapy, and local wound care using standard wound dressings. Angioplasty was carried out if no signs of healing or wound deterioration were observed.

The University of Texas Wound Classification System (UTWCS) was used to classify the *depth* of the wound (grade 1: superficial; grade 2: penetrating to muscle, tendon, or joint capsule; grade 3: penetrating to joint or bone) and for presence of *infection* (stage A: non-ischaemic, non-infected ulcer; stage B: non-ischaemic, infected ulcer; stage C: non-infected, ischaemic ulcer; stage D: infected ischaemic ulcer).[6]

The wound site was recorded before attempted revascularisation. Each wound was assigned to one of the six angiosomes of the foot and ankle following the classical angiosome mapping.[7,8]

The target lesion in the current study was defined as the foot area that needed the widest possible perfusion based on the angiosome concept.

Digital subtraction angiography (DSA) was performed in the course of the intervention and was routinely used to grade lesion severity in leg arteries and assess foot vascularity. Images were reviewed by two senior vascular interventionists. All three crural vessel involvement was a dominant finding in the cohort. The degree of disease in the crural vessels was described by using the Society for Vascular Surgery runoff scoring system grading each tibial vessel as follows: 0 (normal or minimal disease); 1 (21—49% stenosis); 2 (50—99% stenosis); 2.5 (occluded less than halfway); 3 (occluded through most of the length).[5,9] Each tibial vessel was assigned a number from 0 to 3, then 1 was added to the product of the sum of all three leg vessels, resulting in a decimal scoring system from 1 that describes a widely patent runoff to 10 for no major vessel runoff.

The state of foot vascularity was reported in a way to describe the presence or absence of pedal connections that finally fed the target angiosome as follows: “good” if any connection between three leg vessels existed and finally supplied the affected angiosome area; and as “poor” if connections were scarce or absent and recanalisation of the source artery was deemed necessary.

Important arterial—arterial connections around the ankle and foot were evaluated via magnified antero-posterior and angled views. The peroneal artery communicates with the anterior tibial artery via the anterior perforating branch and the lateral malleolar branch, and the peroneal and posterior tibial arteries share three transverse communicating branches. The anterior tibial and posterior tibial arteries communicate directly via the anastomoses of the dorsalis pedis with the lateral plantar arteries (pedal arch).[3]

Endovascular procedure

The revascularisation strategy was angiosome targeted in all cases. First, the source artery directly supplying the target lesion was attempted. Every patient was then assigned to one of two groups: (i) DR when the source vessel was successfully treated; (ii) IR when other leg arteries indirectly feeding the affected angiosome were treated.[10]

Plain balloon angioplasty without stenting was used in all cases. All endovascular procedures were performed under local anaesthesia using a mainly antegrade approach with a 5F sheath from the ipsilateral common femoral artery. Unfractionated heparin (5000 U) was routinely injected after inserting the sheath. The lesion was recanalised with 0.014 or 0.018 CTO wires (V control wire [Boston Scientific, Boston, MA, USA], Glidewire advantage [Terumo Medical

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