

EDITORIAL

Chronic Limb-Threatening Ischaemia (CLTI) Revascularisation: Which Patients Benefit from Endovascular Therapy and Which from Open Bypass?

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Chronic limb-threatening ischaemia (CLTI) represents the most severe clinical manifestation of peripheral arterial disease (PAD), characterised by rest pain, tissue loss, or both, and associated with a markedly elevated risk of limb loss, cardiovascular events, and premature mortality. Patients presenting with CLTI are not defined solely by their arterial pathology; rather, they represent a complex, multimorbid population frequently burdened by diabetes mellitus, chronic kidney disease, coronary artery disease, frailty, and social deprivation. These co-existing conditions profoundly influence both procedural risk and long-term outcomes, and therefore must be central to any revascularisation strategy.^{1,2}

Despite decades of innovation in both surgical and endovascular techniques, the fundamental question remains unresolved: which patients benefit most from endovascular therapy, and which from open surgical bypass? The answer is nuanced, highly individualised, and dependent on anatomical, physiological, and system-level considerations. Importantly, it is also shaped by the evolving evidence base derived from randomised controlled trials.

The original BASIL (Bypass versus Angioplasty in Severe Ischaemia of the Leg) trial was a landmark study that provided the first high-quality evidence comparing bypass surgery with balloon angioplasty in patients with severe limb ischaemia and femoro-popliteal disease.³ Its principal finding - that patients with a life expectancy exceeding two years and suitable anatomy for bypass derive greater long-term benefit from surgical revascularisation - continues to influence contemporary decision-making. However, a critical limitation of BASIL was the absence of a defined or standardised assessment of patient fitness. Clinicians were left to interpret “expected survival” without clear criteria, a challenge that persists in modern

practice.

Equally striking was the poor overall survival observed in BASIL (Bypass versus Angioplasty in Severe Ischaemia of the Leg), a finding that has remained largely unchanged in subsequent trials conducted decades later. BASIL-2, BASIL-3, and BEST-CLI (Best Endovascular versus Best Surgical Therapy in Patients with Critical Limb Ischemia), (major studies published more recently) have all reported similarly sobering mortality rates, despite substantial advances in endovascular technologies, perioperative care, and imaging.⁴⁻⁶ This stagnation in survival highlights a crucial point: revascularisation alone cannot address the systemic atherosclerotic burden that defines CLTI.

Indeed, there is compelling evidence that best medical therapy (BMT) - including antiplatelet agents, statins, blood pressure control, glycaemic optimisation, and smoking cessation - confers a substantial survival benefit in patients with symptomatic PAD.⁷⁻⁹ Yet, real-world data consistently demonstrate suboptimal implementation of these therapies.^{8,9} This therapeutic gap represents a missed opportunity to improve outcomes in a population at exceptionally high cardiovascular risk.

A study by our group CHABLIS (Community and Hospital cAre Bundle to improve the medical treatment of severe claudication and critical limb ischaemia) further reinforces the importance of structured, multidisciplinary care pathways in CLTI.⁹ By integrating vascular intervention with optimisation of medical therapy, wound care, and patient education, and other complex clinical interventions we can meaningfully improve adherence to BMT and overall patient outcomes; this should be the mainstay of CLTI treatment. This underscores that revascularisation should not be viewed in isolation, but as one component of a broader, holistic CLTI-management strategy.

Turning to contemporary trial evidence, the BEST-CLI trial provides critical insights into the comparative effectiveness of surgical and endovascular strategies.⁶ In patients with suitable great saphenous vein conduit and infra-inguinal disease, a bypass-first approach was associated with superior limb-related outcomes compared with endovascular intervention. However, this benefit was contingent upon the availability of high-quality venous conduit. In the absence of such conduit, outcomes between strategies were more closely aligned, highlighting the importance of patient selection.

Similarly, BASIL-3 evaluated endovascular technologies in patients with infrapopliteal disease and CLTI, demonstrating that an endovascular-first strategy is currently the most prag-

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matic approach in this cohort.⁵ While no single device or technique emerged as unequivocally superior, the trial reflects the ongoing evolution of endovascular therapy and its central role in contemporary practice.

It is also important to consider the SWEDEPAD (Swedish Drug-Elution Trial in Peripheral Arterial Disease) trial, which examined drug-coated devices in PAD and CLTI populations.¹⁰ Although not directly comparing surgical and endovascular strategies, its findings contribute to the broader understanding of device safety and efficacy in this space.

Emerging evidence suggests that adjunctive technologies such as vessel preparation - encompassing atherectomy, intra-vascular lithotripsy, and specialty balloons - may enhance the durability of endovascular interventions, particularly in heavily calcified or complex lesions.^{11,12} While these approaches are promising, robust randomised data remain limited, and their role within treatment algorithms continues to evolve.

From a pragmatic standpoint, several principles can be distilled from the available evidence. First, patients with CLTI and femoropopliteal disease who are deemed fit for surgery - based on local or regional assessments, which remain poorly standardised - and who possess suitable autologous venous conduit, are likely to benefit from a bypass-first strategy, particularly in the context of complex or long-segment disease. This approach is supported by BEST-CLI and aligns with the long-term findings of BASIL.

Second, for patients with infrapopliteal disease, an endovascular-first strategy is generally appropriate. This is particularly relevant given the anatomical challenges and the morbidity associated with distal bypass procedures. However, the success of this approach is contingent upon meticulous optimisation of medical therapy and wound care, without which revascularisation alone is unlikely to achieve durable limb salvage.

Third, the concept of patient "fitness" must be refined. Current literature provides little guidance on how best to assess physiological reserve, frailty, or operative risk in this population. There is an urgent need for validated tools that can inform decision-making and ensure that patients are matched to the most appropriate intervention.

Beyond the choice of revascularisation strategy, it is essential to recognise that CLTI care extends far beyond the operating theatre or catheter laboratory. Holistic management is the cornerstone of effective treatment and must include aggressive risk factor modification, structured rehabilitation, and high-quality wound care. Early intervention is also critical; delays in revascularisation are associated with worse outcomes, and a target of intervention within three days of decision-making should be considered a benchmark for best practice.

The economic implications of CLTI management further emphasise the need for effective, durable interventions. Limb salvage strategies, while resource-intensive upfront, are associated with lower long-term costs compared with major amputation, which carries substantial healthcare and societal burdens.^{13,14} Reinterventions, particularly target lesion re-

vascularisations, contribute significantly to overall costs and highlight the importance of selecting the most durable initial strategy.¹⁴

Finally, the importance of ongoing research cannot be overstated. Despite recent advances, many questions remain unanswered, particularly regarding optimal patient selection, the role of emerging technologies, and the integration of medical and interventional therapies. Participation in randomised controlled trials should be considered a fundamental component of CLTI care where available. Moreover, there is a pressing need for continued investment in high-quality research at both national and institutional levels.

In conclusion, the management of CLTI requires a nuanced, patient-centred approach that integrates anatomical considerations with physiological assessment and holistic care. While surgical bypass offers clear benefits in selected patients with suitable conduit and life expectancy, endovascular therapy remains the cornerstone for many, particularly those with infrapopliteal disease or significant comorbidity. Ultimately, the goal is not merely limb salvage, but the preservation of life and quality of life in a population at extreme risk. Achieving this will require not only technical excellence, but also a commitment to comprehensive care and continued scientific enquiry.

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