ASK THE EXPERTS

Predicting the Next Breakthroughs in Limb Salvage and BTK Revascularization

Experts discuss the promise of new and existing technologies for the treatment of CLI patients.

With Andrew Holden, MBChB, FRANZCR, EBIR, ONZM; Leigh Ann O'Banion, MD; and August Ysa, MD, FEBVS

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There are many challenges in the quest to improve below-the-knee (BTK) revascularization outcomes, but predicting the next breakthrough technology is a challenge in itself! The unmet needs include obtaining durable revascularization without restenosis, managing dissection and recoil, crossing and treating calcified lesions, and developing treatment strategies for critical limb ischemia (CLI) patients with dominant small-vessel or microvascular disease. In addition, we need the ability to accurately monitor tissue perfusion during and after a revascularization procedure, which allows objective assessment of the extent of revascularization required to achieve wound healing.

There has been huge interest in drug-coated balloons (DCBs) for BTK arteries, including both paclitaxel- and limus-eluting devices. In the next 2 to 3 years, we should have a clear answer on whether DCBs have a significant benefit over standard angioplasty, as well as which devices work best in BTK arteries. The use of scaffolds or stents to manage recoil and dissection has been largely limited to coronary drug-eluting stents (DESs) for focal disease, although more recently, we've seen promising data with Tack (Philips). Data from new stent technologies, including bioresorbable and self-expanding DESs, will be available in the near future and may expand our ability to optimize outcomes for medium to long lesions. Vessel preparation devices that optimize angioplasty results, minimize dissection and recoil, and improve drug uptake in the vessel wall are being extensively studied in BTK arteries. The results of trials using the Temporary Spur stent system (Reflow Medical) and the Serranator device (Cagent Vascular) will clarify the role of these technologies. Ongoing research in atherectomy and lithotripsy technologies may improve our ability to cross and manage the common problem of calcified BTK arteries. There is also continued clinical research and procedural evolution in deep venous arterialization, and the clinical indications and optimized technique will likely become clearer in upcoming years.

With such diverse and comprehensive research efforts being undertaken to improve BTK revascularization and limb salvage rates, it is difficult to predict a single "next breakthrough" technology. It is likely that the whole toolbox of technologies will improve and evolve to allow us to achieve better and more durable revascularization customized to specific patient needs.

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Over the past decade, vascular surgeons and interventionalists alike have pushed the limits of both open and endovascular techniques in an effort to reduce amputation rates in patients with chronic limb-threatening ischemia (CLTI). However, BTK disease presents a unique challenge, largely due to the lesion characteristics and patient population that this disease is predominantly seen in. BTK disease contributing to CLTI is often seen in patients with longstanding uncontrolled diabetes as well as patients with advanced chronic kidney disease.[1] As a result, the infrageniculate vessels are often heavily calcified, presenting with long lesion lengths, distal disease, and poor runoff, all of which pose significant challenges to treatment.[2]

Rather than choose one big breakthrough, it is more important than ever that we fill our vascular toolboxes with as many technologies as we can, allowing a tailored approach that is individualized to each patient and the disease that they present with. We are at the forefront of some very exciting and critical breakthroughs in BTK disease utilizing drug-eluting technology (Esprit BTK, Abbott) and intravascular lithotripsy (IVL; Shockwave IVL system, Shockwave Medical), both of which have the potential to allow for favorable remodeling and increased patency in heavily calcified severe BTK disease.[3] Use of intravascular ultrasound also allows for appropriate sizing of endovascular treatment for optimal results. Additionally, the LimFlow percutaneous deep vein arterialization system (LimFlow, Inc.) will afford a tool for those patients presenting with the "desert foot" and no apparent options for revascularization.[4] As we advance in our understanding of CLTI and the vast degree and patterns of disease that present in the BTK space, it is crucial that we choose the right tools given the patient's anatomy and clinical severity.

Finally, the surgeon in me cannot go without a reminder that open operative skills are still tucked away in our toolbox. Advanced CLTI with tissue loss often requires pulsatile inflow to the foot for adequate healing and relief of rest pain. Distal tibial/inframalleolar bypasses are still the optimal choice in the appropriately selected patient given adequate cardiovascular risk profile and availability of suitable conduit.[5] The commitment to amputation prevention and treatment of CLTI within the vascular community is ever-expanding, and I am excited for the future, the technologies it will bring, and the improvement in patient outcomes that we will continue to see.

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If we talk about CLTI, the endovascular treatment of the below-the-ankle (BTA) and plantar arch vessels has been the last frontier over the last decade. A large percentage of patients with CLTI have disease of the small-caliber distal vessels, which affects wound healing. Treating this distal disease can therefore improve limb salvage rates.

Endovascular techniques at this level are highly demanding and require dedicated and highly qualified professionals, so it is crucial to master extreme bailout maneuvers and be familiar with new devices that may improve technical success rates.

With the currently available technology and techniques (eg, retrograde access, plantar loop, transcollateral approach), crossing the lesions no longer seems to be the most challenging hurdle for any physician proficient in BTK/BTA revascularization.

Maintaining the patency of these vessels over time is the unmet need in my opinion. The development of plaque modification techniques that can change the ves-

sel wall compliance and enhance antiproliferative drug absorption (eg, atherectomy devices, IVL) may represent a change in the approach to the treatment of complex or calcified lesions; however, robust evidence is scant to broadly implement these procedures. Moreover, improving the navigability and trackability of these devices over the plantar arch is still a work in progress.

On the other hand, with regard to scaffolding, although there is a high level of evidence for the effectiveness of DESs in BTK vessels, this is limited to short segments (usually in the proximal aspect of the vessel). Appropriate mimetic or bioabsorbable technology adapted to the small caliber and longer lengths of these vessels would definitely be advantageous. Needless to say, a dedicated stent for the BTA segment that takes into account all the features and forces involved in such a specific location could be a major breakthrough.

In addition, if we think of frontiers to conquer, we mustn't forget that even today, there is a percentage of patients with CLI for whom conventional revascularization treatments cannot provide an answer (chronic renal failure, hemodialysis, severe calcifications, small artery disease–medial arterial calcification, etc). In this subgroup of patients, venous arterialization techniques offer promising results and could become realistic alternatives to undergoing a major leg amputation. Hopefully the outcomes of the ongoing trials will refine the indication in such group of patients and will answer the questions of who, when, and why.

If my imagination is allowed to run free, I have always wondered why highly sophisticated technology has been put at the service of complex aortic endovascular procedures, while BTK/BTA operators remain as sort of "artisans" as we perform our cases. Specific tools to help in vessel navigation (eg, mimicking fusion technology) for long occluded segments or in the arch that would avoid such dependency on the physicians' skills might be extremely useful, improving and universalizing procedure success rates. Finally, why not go a little bit further with an automated wire spinner device? If we could multiplicate the rpm of our drilling movement in a controlled way, it seems intuitive to think that this would massively improve the penetration power of our chronic total occlusion wires.

Technology has greatly improved our outcomes regarding CLTI endovascular treatments over the last decade. New "game changers" are yet to come—and we are already looking forward to them. ■