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 have 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 arteri- alization, 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.
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. 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.

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 technologies (eg, retrograde access, plantar loop, transcatheter aortic valve implantation), plaque modification techniques that can change the vessels, which affect 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, transcatheter 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 vessels, which affect wound healing. Treating this distal disease can therefore improve limb salvage rates.

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.