Tack Scaffolding for Below-the-Knee Dissection Treatment: A Therapeutic and Cost-Effective Strategy

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Chronic limb threatening ischemia (CLTI) remains a challenging problem, associated with both significant morbidity and mortality. Effective interventions, especially among those patients with complex infrapopliteal disease, have been limited. Reasons for failure are multifactorial including the nature of disease, calcification, vessel recoil, and arterial dissection.

Cao et al have published one of the first exploratory health economic analyses suggesting the cost-benefit of the Tack scaffolding system in infrapopliteal disease.[1] Arterial dissection is fundamental to percutaneous transluminal angioplasty (PTA). PTA results in fracturing of plaque, destruction of endothelial elements, tearing of the internal elastic lamina, medial trauma, and stretch of the adventitia.[2-4] Dissections are often seen after small vessel angioplasty and complex lesion intervention (TASC II C/D).[5] Higher rates of target lesion revascularization (TLR) are seen with persistent dissections, especially with deep adventitial injury.[6,7]

Dissection Treatment Challenges

Treatment options for below-the-knee (BTK) disease are limited. Balloon-expandable, drug-eluting stents (DES) indicated for coronary intervention, have shown efficacy in the proximal third of the calf, but risk structural compromise in more distal segments.[8] The use of coronary paclitaxel DES in the PADI trial was also shown to be cost-effective, primary via reduced hospital costs related to amputation and rehabilitation in the CLTI population.[9]

Several scaffolds remain under investigation. The bare-metal Micro-Stent (Micro Medical, Inc), is a biomimetic, woven scaffold that has been studied vs PTA within the STAND trial, the results of which are forthcoming. The SAVAL BTK stent (Boston Scientific) is a paclitaxel, self-expanding, drug-eluting stent that unfortunately failed to reach superiority over PTA at 12 months, nor did it reach non-inferiority on safety.[10] The Espirit BTK stent (Abbott Vascular) is a bioresorbable, sirolimus-eluting scaffold with hybrid features between a balloon-expandable and self-expanding stent, the results of which will hopefully be presented later this year. However, there remains a paucity of data in the device literature regarding dissection management as significant dissections are often excluded from interventional studies. Tack is the first, indicated, purpose-built scaffold for dissection.

The Tack Endovascular System (Philips) combines minimal metal scaffolding via a short implant, and very low, outward radial force. This device is not for recoil, but allows tears to be tented open facilitating healing with minimal trauma and inflammation, resulting in a reduced intimal hyperplastic response.

The BTK Tack system consists of four implants (6 mm length; 1.5-4.5 mm vessel diameter) on an 0.014″ platform with adaptive sizing. These are indicated for use in small popliteal arteries (P2/P3 segment) or tibial vessels to above the tibiotalar joint. The TOBA II BTK trial looked at complex disease (47.6% with chronic total occlusions).[11] Tacked segment patency was noted to be 81.3%, limb salvage was 96.8%, freedom from CD-TLR was 83.1%, and amputation-free survival was 89.3% at 12 months.[11] Even out at three years, TOBA II BTK reported a remarkable 93.9% target limb salvage and 69.6% freedom from CD-TLR.[12]

Adoption

Despite availability of proven technology, dissection management remains varied among operators. In general, there does not appear to be consensus what constitutes a significant flow-limiting dissection. Angiographic grading is based on an almost 40-year-old classification system intended for use in coronary arteries.[13] A single view of the lesion may miss a lesion orthogonal to the imaging plane. Imaging of BTK lesions becomes even more challenging given their small size (typically <4 mm).

Intravascular ultrasound (IVUS) which was not mandated in

the TOBA II BTK study, can make it easier to identify these lesions in three-dimensional space, especially when incorporating flow mapping technologies (eg, Chromaflow [Philips]). IVUS also now has significant societal support. In a recent consensus document, IVUS use for tibial interventions had uniform support for use across all surveyed, multidisciplinary experts.[14] Moreover, use of IVUS was also noted to result a lower risk major adverse limb events (MALE) in a retrospective review of peripheral procedures in a large Medicare population.[15] IVUS grading systems for dissection do exist, but do not have widespread adoption.[16] Consensus on definitions for significant dissection will help improve adoption of dissection treatment strategies.

In general, dissections can be identified and marked via manual co-registration with fluoroscopy and orthogonal angiography and/or IVUS. Short ≤ 1 cm dissections can be addressed with a single Tack, a 1-2 cm dissection with Tacks on either end of the entry and exit tear, while longer dissections can be addressed with Tacks placed with a 4-5 mm gap. When placed too far apart, Tacks may not offer sufficient scaffolding, and this may impact patency.

As Tacks lack significant radial force, IVUS may also identify significant recoil or inadequate debulking where alternate treatment strategies may be more effective. At the ostium of the tibial arteries, this may include balloon expandable coronary stents, but elsewhere in the infrapopliteal vessels, adjunctive vessel preparation tools including atherectomy and/or focal force balloons may be beneficial. Certainly Tacks can be used after adequate vessel preparation.

These technologies do add to the overall cost of performing the limb salvage procedure. The Tack delivery system itself is considerably more expensive than contemporary, coronary DES, albeit with the ability to be deployed in regions not appropriate for long balloon-expandable scaffolds. However, as TOBA II BTK did show that there was improved amputation-free survival and high rate of target limb salvage, the overall cost savings are driven by reduction in the high long-term costs associated with amputation.

Future Directions

Interest in the infrapopliteal space is high given the limited options available for CLTI patients with durable results. The current iteration of the BTK Tack system is limited to 4 implants, but often dissections can be diffuse. A future platform with more implants may be beneficial and more cost-effective with minimal increase in complexity of the delivery system. Given the strong data supporting drug elution in the BTK space from the coronary literature, perhaps a drug-eluting Tack would also confer some benefit as well. But given the perceived failure of the SAVAL platform, this may not be entirely clear. Was it the drug choice (paclitaxel), the longer length and single size of scaffolding (3.5 mm x 80 mm), more complex lesions in the DES cohort, or comprehensive angioplasty protocol that produced the insufficient outcome?[10] As these patients will be followed out to 5 years, more clarity may be gleaned from this population over time.

We also now have 2 contemporary, major studies that have reached, on the surface, different conclusions regarding either a surgical or endovascular first strategy for CLTI patients. BEST-CLI has suggested that in patients with adequate vein conduit, vein bypass is superior to endovascular intervention with lower major adverse limb events and death (composite endpoint).[17] BEST-CLI did include patients without infrapopliteal disease, suggesting a less complex patient cohort. Moreover, controversy exists whether the endovascular strategies employed represented optimal intervention, with high technical failure seen in 15.3% vs only 1.7% in the surgical group.[17] It will remain to be seen in future publications what were the early and late failure modes of intervention for those who underwent endovascular approaches, including the numbers of those patients with significant residual dissections. BASIL-2, in a CLTI population, found that endovascular intervention of infrapopliteal disease was superior to surgery, driven by lower mortality and amputation-free survival, despite higher rates of reintervention. CLTI patients have complex disease and reintervention is common leading to higher cost, but novel technologies and approaches to this disease offer significant potential benefits to both patients and the system as a whole.

The TOBA II BTK study was perhaps the largest of its kind to show sustained outcomes for limb salvage in a largely CLTI population. This cost-effective analysis adds to the literature supporting the treatment modality from an economic perspective. A similar approach may also be beneficial for looking at the TOBA above-the-knee (ATK) cohort, especially the TOBA III dataset where the combination of ATK Tack (Philips) and IN.PACT Admiral (Medtronic, Inc) drug-coated balloon angioplasty was found to have impressive patency rates of 95%, and 97.5% freedom from clinically driven target lesion revascularization at 12 months.[18] Successful findings also were demonstrated in the long lesion cohort.[19] These results are perhaps superior to 12 months results from contemporary self-expanding DES, though direct comparison cannot be made.[20] In the ATK population, cost-effectiveness may differ between claudicants and patients with CLTI and warrants further investigation.

Dissections are common and further prospective studies will be necessary to identify those patients who will most-benefit from these specialized therapies.

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