

INTERVIEW

The TOBA II BTK Trial: A Sub-Analysis of the Long Lesion

An Interview With Lawrence Garcia, MD

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Vascular Care Group and Newton Wellesley Hospital at Tufts University School of Medicine, Wellesley, Massachusetts

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At the 2023 Amputation Prevention Symposium (AMP), cardiologist Lawrence Garcia, MD, from the Vascular Care Group and Newton Wellesley Hospital at Tufts University School of Medicine in Wellesley, Massachusetts, presented a review of the findings from Tack Optimized Balloon Angioplasty Study of the Tack Endovascular System in Below-the-Knee Arteries (TOBA II BTK) trial. This prospective, multicenter, single-arm, nonblinded study investigated the safety and efficacy of the Tack Endovascular System (Philips) in the mid/distal popliteal, tibial, and peroneal arteries ranging in diameter from 1.5 mm to 4.5 mm for the treatment of post percutaneous transluminal balloon angioplasty (PTA) dissections requiring repair.

Vascular Disease Management spoke with Dr. Garcia to discuss his presentation.

Dr. Garcia, tell us about your presentation on the TOBA II BTK trial.

My presentation is about use of the Tack Endovascular System, which has been around for a few years and recently received FDA approval for use both above and below the knee (BTK).

Everybody uses similar devices for a myriad of arterial lesions. When it's above the knee, we're either leaving nothing behind or leaving something behind. When leaving something behind, it's almost always a stent, and that stent usually has a length that will cover the entire lesion. If you use a drug-coated balloon (DCB), you leave nothing behind. In both of those procedures, there are potentially edge events or, particularly when you leave nothing behind with just simple balloon work, there are some dissection zones.

The developer of the Tack Endovascular System, Dr. Peter Schneider, developed an accordion approach to this stent—actually, a *scaffold* is a better way to look at it. That accordion, unlike a stent that has a certain length and has a particular size, expands itself to the size of the vessel that it's in with limited risk of invagination of the scaffold due to a constrained expansion. So they could have made the scaffold short or long, but they decided to go short, which I think is fine because now you can tack up, hence the term *tack*, these little areas of dissection. It works very well for above the knee.

The same idea for these tacks and the accordion design works for BTK, so the BTK trial showed benefit in an area where no one device has been shown to be beneficial for BTK lesions short of simple angioplasty. Your ability to put this scaffold in a short segment to tack up those dissections or disruptions in the artery gives you the benefit of longer duration patency, which then may afford you better wound healing and ultimately limb salvage. The BTK trial showed benefit on short tacks to maintain patency durability to that vessel location.

I also talk about the longer lesion subset analysis, when you go in the longer lesion segments. The downside to any stenting trial, any lesion trial, whether it be angioplasty or DCB, has been as you go longer, you have more chances to fail. Here, the BTK trial for Tack has shown that its benefit is its short segment coverage. You don't have to stent the entire length of a lesion, just the area of dissection. The Tack in and of itself is about 1 cm in length, and the total Tack length of dissection is about 1.5 cm. So at the end of the day, you don't have to do the whole 8 cm or longer lesions you just treated; rather, you just focus on the places that look dissected. The benefit is its long-term patency, which is great.

Better and alternative devices are all well and good; however, I really want us to see better devices that then go head-to-head in direct trials and see what works. Ultimately, we need a better outcome when it comes to BTK. I think we need to define not only the BTK patient, but is it all the same type of patient? We need to have a very specific group because all comers with, let's say, rest pain or Rutherford 4 limb loss, tissue loss, are not the same from patient A to B to C. We need to really focus on getting all As in the same group so we can actually have a meaningful outcome. Because right now, no trial has really shown that they're beneficial in all comers when it comes to BTK.

So that should be the next step, the next study?

No doubt. I think it would be awesome if we had a trial and a trial design that says, look, if we're going to use a study device and our predicate is going to be angioplasty ... I've always championed this idea and what I would love to see is that we focus on short lesion, long lesion, whatever you want to focus on regarding lesion length—but stick with it. If the target is, let's say, the anterior tibial, then your device has to go into the anterior tibial. If the anterior tibial is not a target, then that's not a subject to enroll in the trial. Because you fix the peroneal or the posterior tibial (PT) it doesn't necessarily mean that's the right choice to study the protocol device. It's not a wrong choice; you have to fix what's right for the patient. But for this trial and the spirit of the trial, this patient probably doesn't get enrolled.

If we're fixing the anterior tibial (AT), I'd really want us to fix the AT with the device. If you fix it with the AT but then you work on the other vessels like the peroneal or PT, then that patient shouldn't be enrolled in this trial because we're finding that other arteries that get fixed can still heal a wound, but your device may not be patent. We really need to focus on very specific patients and start simple and then grow from there.

What is the one takeaway that you want attendees to get from your presentation?

What I think people should take away from my presentation is that the Tack should be part of your armamentarium when it comes to BTK work. If you have it on your shelf, learn how to use it and develop a fairly good algorithm in your mind, like for any other device, as to when to pull the trigger on its use. ■

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