

# Stenting Lesions in Distal Anatomy

Perspective on a modern-day treatment algorithm.

WITH MARTIN WERNER, MD



## How would you define the modern clinical treatment algorithm for popliteal disease?

In the last few years, drug-coated balloons (DCBs) have changed how we treat popliteal lesions and a leave-nothing-behind treatment approach has evolved. I, along with many physicians, tend to use fewer stents. I try to avoid full-metal jackets and full-lesion covers with stents, and I only use stents in certain situations. However, we have learned from DCB trials, randomized trials, and other registries that there are always patients who need mechanical stabilization. This is the main disadvantage of DCBs. They do not give you the mechanical stabilization you need, particularly in calcified or long lesions. Depending on lesion length, you may need stents even when working primarily with DCBs.

**“PREDILATION IS AN IMPORTANT PART OF OUR TREATMENT ALGORITHM. WE PREDILATE THE BALLOON FOR 60 SECONDS AND WE MEASURE THE BALLOON PRECISELY TO AT LEAST A RATIO OF 1:1 BALLOON-TO-VESSEL SIZING.”**

In our hospital, we first treat patients with standard balloon dilation to see how the vessel reacts. If the vessel opens up wide without dissections or recoil, we call this a *percutaneous transluminal angioplasty (PTA) responder*. The patient is then treated with DCBs. When a patient does not respond well to predilation, we call this a *PTA nonresponder* and will use a stent. In our daily practice, 80% of cases are PTA responders and around 20% are PTA nonresponders.

Predilation is an important part of our treatment algorithm. We predilate the balloon for 60 seconds and we measure the balloon precisely to at least a ratio of 1:1 balloon-to-vessel sizing. With this algorithm, we are able to define patients who need a stent and patients who will do well without one (Figure 1). Currently, there are no data on whether longer predilation time leads to less of a need for stenting, although my colleagues and I have found it to be true in our experience. From personal

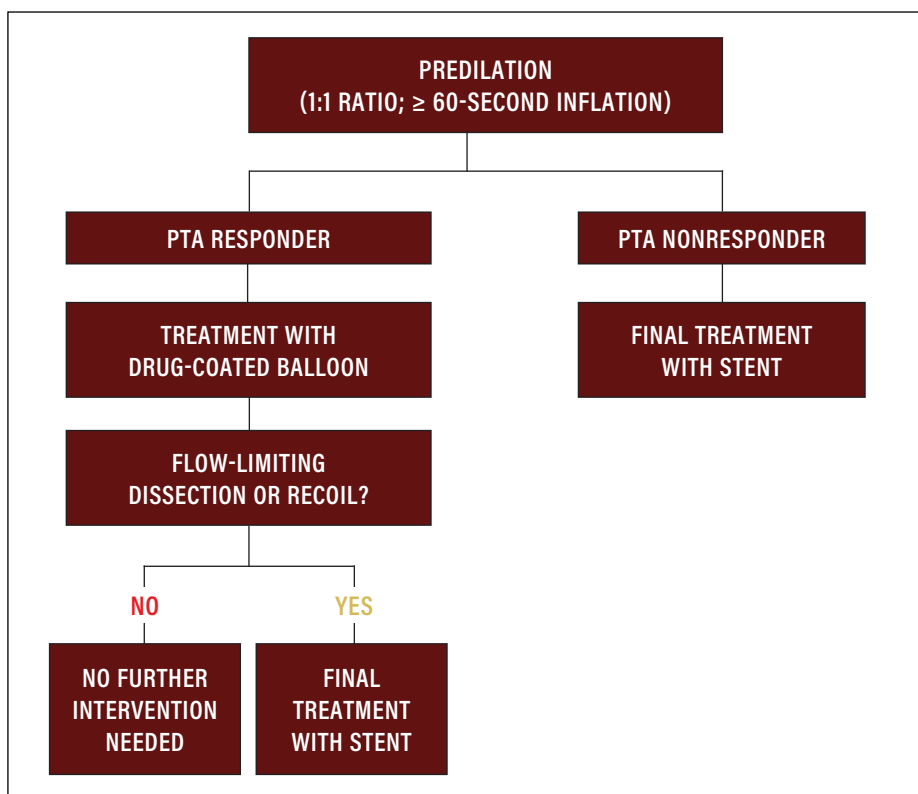


Figure 1. Treatment algorithm for lesions in the superficial femoral artery or popliteal artery.

experience, dilating for 10 seconds will not usually yield good results. The necessity of proper predilation is getting more attention in the scientific community and should be further scientifically investigated. Proper predilation is not only important before DCB treatment, but also before stent placement in order to achieve proper stent apposition of self-expanding stents in the superficial femoral artery (SFA).

### **What factors led to your choice of the GORE® TIGRIS® Vascular Stent as your treatment method for popliteal disease?**

Because of this stent's unique features, you can place the stent from the proximal SFA to the proximal segment of the popliteal artery, where there is a lot of vessel motion during leg movement. A few years ago, the popliteal artery was a "no stent zone." But with this modern generation of stents, you can cover those regions where previous-generation stents would have fractured. Our experience with the GORE TIGRIS Vascular Stent, as well as data from the GORE TIGRIS IDE Trial, show that there are no stent fractures with the GORE TIGRIS Vascular Stent in the femoropopliteal segment after 1 year.<sup>1</sup>

### **What unique benefit does the GORE TIGRIS Vascular Stent provide as compared with other options?**

The stent is not only composed of nitinol, but it also has expanded polytetrafluoroethylene interconnectors. This is unique to all the other competitors in that field, which are usually nitinol only. Another benefit is that, in our study, there were no device-related complications, no geographic misses, and no need to use a second stent in any of the patients.

### **How did you structure the design of the Austrian TIGRIS Registry?**

The GORE TIGRIS Vascular Stent has a maximum length of 10 cm, so we included patients who we were able to treat with one stent. Patients with lesions < 8 cm consented and were enrolled in the study if predilation did not show a good response. We enrolled 100 "PTA nonresponder" lesions in 97 patients and have 1-year follow-up available for all patients; 2-year follow-up is ongoing.

### **What are the best practices necessary to achieve the outcomes you experienced?**

First, always predilate, even when using a stent. Second, ensure that stents are appropriately sized. The GORE

TIGRIS Vascular Stent instructions for use recommends oversizing the stent just 5% to 20% relative to the artery. Analysis of the angiographic data shows that we accomplished that ratio. I have two techniques to ensure appropriate sizing. For the first technique, I use the balloon as a visual assessment. If I have a good impression from the balloon, that is enough for me to choose the stent size. If I am not sure, my second technique is to use quantitative measurements.

Third, confirm full-lesion coverage so there is no geographic miss or stent misplacement. The GORE TIGRIS Vascular Stent helped us achieve that because it does not jump forward or backward. It stays where you intend to deploy it. This feature makes it very easy to use.

### **What were the most noteworthy conclusions from the study, for both physicians and patients?**

We observed a 12-month primary patency rate of 92.9%. Freedom from target lesion revascularization at 12 months was 94.9%. Physicians should know this is a highly effective therapy for patients needing stenting in short lesions in the SFA or the popliteal artery—those segments that undergo a lot of motion. The few stents that had restenosis were easily treated, so secondary patency was 100% at 1 year. Hemodynamic and clinical improvement was evident for the vast majority of patients. The main message to take away from this study: If you need a stent in the SFA or popliteal artery, we have a very efficient and easy-to-use device right now.

Patients should know that there is no need to worry about stenting in the proximal popliteal artery. The GORE TIGRIS Vascular Stent is specifically intended for those flexible segments, so patients will be able to lead an active lifestyle. ■

1. Laird JR. Novel nitinol stent for long lesions in the superficial femoral artery and proximal popliteal artery: 24 month results from the TIGRIS Randomized Trial. Presented at VIVA 2016: Vascular Interventional Advances Conference; September 18-22, 2016; Las Vegas, NV.

#### **Martin Werner, MD**

Head of Department of Angiology  
University of Vienna  
Hanusch Hospital  
Vienna, Austria  
martin.werner@wgkk.at

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