The VIRTUS Feasibility Trial

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INTRODUCTION

Veniti's Vici stent is a dedicated venous stent and has properties that are different from arterial properties in terms of crush resistance and lumen quality. This makes it much more applicable to those lesions that are thrombotic or non-thrombotic (for example, in patients with May-Thurner Syndrome).

The Vici stent was properly engineered for venous use. It has significant properties added to it that make it completely different than an arterial stent. First, it is self expanding and second, it has a significant amount of strength so that it's crush resistant and has sufficient radial resistive force. The pathology of veins is different than in arteries, so venous stents must have differences in terms of point load. For example, in cases of May-Thurner syndrome (iliac vein compression syndrome), the stent must resist focal loads, so the crush resistance needs to be significant. In terms of the stent design, the Vici stent is a closed-cell stent, which has certain properties that are advantageous over an open-cell stent or hybrid stent. There are trade-offs in terms of benefits, but if we look at all the benefits for this particular stent design, they far outweigh any open stent or hybrid stent that's currently on the market.

The learning curve for the Vici venous stent is quite short. If you have implanted any arterial or venous stents before the Vici venous stent, you'll find it has similar deployment qualities. The foreshortening is minimal and it's predictable, from delivery system to the vein, so the operator knows where the stent is going to land.

VIRTUS FEASIBILITY STUDY

The first 30 patients were entered into a feasibility trial, and the results were remarkable. At 12-month follow-up completed by duplex and venogram, there was a 100% patency rate of non-thrombotic lesions found in May-Thurner Syndrome patients. The thrombotic results were a little bit less at 79%, but with secondary patency achieving 95%. The complication rates were minimal and there were no adverse safety events, so this procedure appears to be safe. These results are impressive, but it's more important to ask how the patients really fared with these procedures. In other words, how did the patients really feel after the stent procedure? When we look at venous clinical severity score, with those patients who achieved at least a 2-point improvement, 85% had relief at 1 year in terms of pain, and that's remarkable. Thus, the feasibility trial is now closed.

FUTURE STUDIES

The VIRTUS trial is a multicenter, prospective, single arm, non-randomized study to evaluate safety and efficacy of the Veniti Vici Venous Stent System in relation to pre-defined objective performance goals (ClinicalTrials.gov Identifier: NCT02112877). The entire trial involves 200 patients, of which 75% were thrombotics and 25% were non-thrombotics. The 1-year data from the Virtus trial will probably be out in 2018.

DISCUSSION

One of the things that's notable about venous intervention is that for a long time, we didn't look northward in terms of May-Thurner syndrome. It became obvious to us that in patients who had thrombotic events, there were obstructions cephalad to the lower extremities. When we looked at C5 and C6 disease, we noticed that there was an abundance of obstructive lesions in the common iliac or external iliac that we never accounted for in the past. So now when we look for patients who have C5 and C6 disease, and even C4B disease, there's a significant amount of patients who have obstructive phenomenon, whether it be May-Thurner syndrome or whether it be thrombotic lesions. With the ease of this procedure, I think we are going to help a lot of patients. Certainly regarding how the patients feel in terms of the venous clinical severity score, in terms of pain only, we've shown that 85% have reduced their pain at 1 year.

I believe that the Vici venous stent is an easy, applicable stent without a big learning curve. There really is no specific trick in terms of stent implantation. I certainly rely heavily on intravascular ultrasound, which is very important for both diagnosis and stent sizing. We did notice that the Vici venous stent foreshortens in the caudal position, but not much. It is easy to deploy and release the stent using a pin-and-pull method, so it really is not different from any other stents except it's easier. Non-venous stents such as the Wallstent, on the other hand, often have significant foreshortening and unpredictable landing.