Sponsored by Cook Medical

PERIPHERAL ARTERIAL DISEASE

Satisfying the Practitioner's Need for Long-Term Data, Transparency

With John Phillips, MD; Venita Chandra, MD; and Michael Wilderman, MD, FACS

John Phillips, MD
System Director
OhioHealth Heart and Vascular Physicians
Columbus, Ohio
Disclosures: Speakers bureau/consultant/advisory board for Cook Medical, Boston Scientific Corporation, Medtronic, CSI, BD Bard, and Philips.

Venita Chandra, MD
Clinical Associate Professor of Surgery
Stanford University School of Medicine
Stanford, California
Disclosures: Speakers bureau/consultant/advisory board for Cook Medical, Medtronic, Abbott, Shockwave, Penumbra, Gore, and Alucent.

Michael Wilderman, MD, FACS
Chief of Endovascular Surgery
Hackensack University Medical Center
Hackensack, New Jersey
Disclosures: Consultant for Cook Medical, Gore, and VTI.

Is data transparency important when choosing a superficial femoral artery treatment?

Dr. Phillips: Certainly, but the devil is in the details. Thankfully, we have a lot of options when treating the femoropopliteal region, but at the end of the day, we want to know the intervention will be safe, efficacious, and durable. There are a lot of data out there—some of it good, some of it not so good. Physicians have a fiduciary responsibility to be as informed as possible. Likewise, our industry colleagues have the responsibility to provide us with the highest level of quality data with the longest possible time frame. If we have learned nothing else from the paclitaxel mortality concern, it is that we need more patient-level data and more long-term follow-up with any treatment modality we use.

Dr. Chandra: Data transparency is always important. It is so easy to shape data or present data in a way to make a point, but it is our responsibility as vascular interventionalists/surgeons to look closely at the data and make our own decisions about what they mean and how they will impact our practice.

Dr. Wilderman: Every time I take care of a patient, I care about both the short- and long-term outcome. This is even more important when I'm implanting a stent inside a patient. For any given clinical scenario, I am to use the device with the best short- and long-term results. Therefore, clinical data and personal experience are of the utmost importance to me. One of the challenges in the peripheral vascular space is that not all trials use the same endpoints or time lines. It can be difficult to compare devices head to head because of many confounding factors. Therefore, the better, longer, and more transparent a particular data set is, the easier it is for me to interpret and take to clinical practice.

How has the fear of increased paclitaxel mortality impacted your practice?

Dr. Phillips: My practice and the practice of our health system were initially impacted, as I imagine most were. However, as more patient-level data came out and the hazard ratio continued to shrink, my fears with respect to increased mortality risk when using paclitaxel, whether it be with a balloon or stent, were assuaged. Ultimately, in my opinion, the recently published data in the SWEDEPAD trial put this issue to rest for me.[1] I have always believed that the use of paclitaxel in either a balloon or stent produces more durable results with a similar safety profile to nonpaclitaxel–based products.

Dr. Chandra: It no longer affects my practice. Certainly, when the Katsanos et al paper first came out,[2] everyone

Sponsored by Cook Medical

needed to pause and take a deep dive into the issue. Ultimately, I think with larger amounts of patient-level data, there really is no longer any sign of a concerning signal when it comes to mortality. Given the significant efficacy data, my practice has gone back to the liberal use of drug-eluting technologies.

Dr. Wilderman: When Katsanos and his team reported an increase in late all-cause mortality in patients treated with paclitaxel-coated devices, the peripheral vascular world was shaken. We knew that these devices clearly outperformed noncoated devices in terms of patency, but increased mortality? The FDA issued a warning letter, hospitals were pulling products, and patients were concerned. Since then, the data has been reevaluated. In the Zilver PTX trial from Cook Inc., the initial published mortality results were reported based on the primary randomization and grouped based on the initial intent-to-treat groupings. The investigators later reported that 40% of the primary angioplasty group were actually treated with Zilver PTX (Cook Medical) in secondary randomization and crossover. If these patients were actually placed in the PTX group, there would have been no difference in mortality between the two groups.[3] Moreover, since that paper, others have found no increased mortality with paclitaxel-coated devices. As more and better data have become available, it has become easier to ease our patient's fears and concerns. Most patients now want me to do whatever I think is best for them, even if that means using a drug-coated device.

Do you feel like you have all the tools you need to treat critical limb ischemia (CLI)?

Dr. Phillips: I believe we are getting close, and the future is bright for treating CLI, particularly below the knee. I would like to see a dedicated scaffold with an antiproliferative agent for the tibial vessels. However, in general, I feel that both the wire technology and crossing catheter advances have truly changed our ability to cross these long, complex lesions. Also, the ability to modify the plaque, whether it be with a specialized balloon or atherectomy device, continues to improve our short-term results. Finally, we now have a dedicated device to treat dissections that occur after balloon angioplasty, and hopefully more devices will come to market to provide even more durable results. Ultimately, I believe we are much better off now than we were 5 years ago, and these patients who are the sickest of the sick with the highest mortality rate are the ones who are benefiting the most.

Dr. Chandra: We have made great strides and dramatically evolved our armamentarium of tools for CLI patients, but we still have a long way to go. Durable management of long chronic total occlusions and heavily calcified lesions and management of significant distal small-vessel disease/pedal arch disease are areas where we continue to need new tools.

Dr. Wilderman: CLI is a challenge, and unfortunately, many patients present too late in their disease course. We are still missing certain tools, the main being stents (with or without drug coating) designed for tibial vessels. Although some people prefer drug-coated balloons and atherectomy devices, I think that durable stents made for tibial vessels will be of great clinical significance to outcomes in the treatment of CLI.

Eluvia (Boston Scientific Corporation) 3-year data have still not been presented; has this affected your practice?

Dr. Phillips: Not at this point. However, the Zilver PTX stent is the torchbearer for drug-eluting stents (DESs) in the femoropopliteal segment. It has been on the market the longest and therefore has the most longitudinal data. Because of this, all other stents with paclitaxel, and balloons for that matter, will be judged against the Zilver PTX DES. We now have two paclitaxel DESs for this region, both of which have raised the bar in terms of patency and reduction of clinically driven lesion revascularization rates. In my opinion, these facts cannot be understated and should be celebrated as we continue to move forward to develop durable technology to treat this very complex anatomy.

Dr. Chandra: It is difficult to be the later player in the field. As such, Eluvia does not have a significant role in my practice because (A) it was not the first tool out there, and (B) its lack of longer-term data can't compete with the current players that are clearly proven to be safe and efficacious.

Dr. Wilderman: I have had great long-term success with Zilver PTX when I wish to use a drug-coated stent. The investigators have published outstanding 5-year data, and I have a large personal series as well with outstanding outcomes. For me to change to a new device, I would want to see as good, if not better, long-term outcomes in their clinical trial. Moreover, I would also want to see real-world data. The fact that the medium- and long-term Eluvia trial data have not yet been published makes me pause when selecting that stent over others with more long-term follow-up data.

Has concern of hypoechogenic halo, aneurysmal degeneration, persistent inflammation, negative

late lumen loss, persistent shadowing, positive remodeling, or aneurysm formation influenced your DES decision?

Dr. Phillips: Any time there are possible concerns raised about the durability of a device and/or negative architectural changes that may occur within said device or the surrounding vessel, we should take pause and reassess things. I believe we should look at the data closely and make the most informed decision on a case-by-case basis regarding what type of DES to implant. Although the data are statistically similar through 2 years, the Eluvia stent and Zilver PTX stent have differences with respect to their design and elution of paclitaxel. I do not believe that we have cornered the market on what the perfect antiproliferative agent is, how it should be impregnated on a stent, or how it is eluted over time. However, great strides have been made with respect to this technology, and we will continue to improve and develop new treatment modalities for the femoropopliteal segment and the tibial arteries.

Dr. Chandra: Yes, these findings are certainly concerning. It will be important to see the longer-term sequelae of these issues. As we have seen with the Katsanos et al paper, concerns occasionally present themselves and are later realized to not be an issue. However, it is hard to argue that such findings are acceptable. For now, I would not readily use a DES with such complications, especially when there are data on another commercially available DES with long-term efficacy and safety data.

Dr. Wilderman: Any device can have complications associated with it, and peripheral stents are no different. There have been reports of aneurysmal degeneration and halos after DES placement, but I have not seen it in clinical practice. I have placed hundreds of DESs over the years, and we participated in a large single-center registry. Our real-world results were similar to other large registries, and we did not have any patients with aneurysmal degeneration. For me, the most important thing is stent patency and freedom from symptoms and reinterventions. In my practice, DESs have performed the best, and I am not willing to compromise. ■

1. Nordanstig J, James S, Andersson M, et al. Mortality with paclitaxel-coated devices in peripheral artery disease. N Engl J Med. 2020;383:538-2546. doi: 10.1056/NEJMoa2005206
2. Katsanos K, Spiliopoulos S, Kitrou P, et al. Risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the leg: a systematic review and meta-analysis of randomized controlled trials. J Am Heart Assoc. 2018;7:e011245. doi: 10.1161/JAHA.118.011245
3. Dake MD, Ansel GM, Bosiers M, et al. Paclitaxel-coated Zilver PTX drug-eluting stent treatment does not result in increased long-term all-cause mortality compared to uncoated devices. Cardiovasc Intervent Radiol. 2020;43:8-19. doi: 10.1007/s00270-019-02324-4