Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist

PERIPHERAL INTERVENTIONS

The Use of the Highlander™ 014 PTA Balloon Dilatation Catheter in the Treatment of Peripheral Artery Disease

CLD talks with Vishal Kapur, MD, FACC, FSCAI, RPVI.

What are some of the challenges of treating peripheral artery disease (PAD), particularly below the knee?

PAD is an underappreciated and underdiagnosed disease. It is considered as a coronary artery disease equivalent and hence warrants importance, especially in those patients who have critical limb ischemia (CLI). CLI patients have a significantly higher chance of amputation and of those patients who undergo amputation, half usually die within a year.

continued on page 14

Happy Cardiovascular Professionals Week!
February 11-17, 2024

In This Issue

Do We Need to Withhold Jardiance (SGLT2 Inhibitors) or Ozempic (GLP-1 Agonists) Before Cardiac Cath?

Dr. Morton Kern with Drs. David Cohen, Kirk Garratt, Spencer King, Neal Kleiman, Srihari Naidu, Matthew Price, Steve Ramee, Chet Rihal, and Bonnie Weiner.

page 6

Crossing Severely Stenotic and Tortuous Complex Lesions With Ease — Two New Devices Facilitate Successful Outcomes

Eric A. Secemsky, MD, MSc, RPVI; Killian J. McCarthy, MB BCh BAO

page 20

PATIENT CARE

End-Tidal CO_2 Monitoring for Respiratory Adverse Events During Procedural Sedation: An Additional Layer of Safety

CLD talks with Arnold H. Seto, MD, MPA, FSCAI.

In today's cardiac catheterization laboratory environment, why is end-tidal CO_2 monitoring becoming more important?

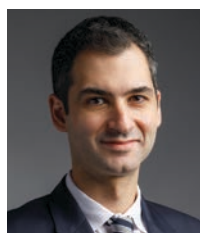
End-tidal CO_2 ($EtCO_2$) measures the level of carbon dioxide that is released at the end of exhalation. Since the exhaled CO_2 is much higher than the level in ambient air, $EtCO_2$ is a sensitive marker of ventilatory effort, much more so than pulse oximetry, which might only decline several minutes after apnea occurs.[1]

continued on page 10

CALCIUM CORNER

A Physician's Perspective on New Permanent Reimbursement Pathways for Coronary Intravascular Lithotripsy

CLD talks with Yousif Ahmad, BMedSci, BMBS, MRCP, PhD, FSCAI, FACC.



How did the previous, temporary reimbursement pathways impact intravascular lithotripsy (IVL) utilization within your practice?

The previous IVL codes were temporary pathways as part of a breakthrough technology designation from Centers for Medicare and Medicaid (CMS). The two pathways were New Technology Add-on Payment (NTAP) or Transitional Pass-Through (TPT). These codes were helpful in that they allowed IVL technology to reach the market and allowed the cost of the device to be accounted for. You weren't losing money by using IVL, so the previous codes were very beneficial from that perspective.

continued on page 12

Continued from cover

The Use of the Highlander™ 014 PTA Balloon Dilatation Catheter in the Treatment of Peripheral Artery Disease

CLD talks with Vishal Kapur, MD, FACC, FSCAI, RPVI.

The Highlander™ 014 PTA Balloon Dilatation Catheter works well in the type of non-focal lesions we typically see in our below-knee interventions, which is why we prefer it as one of our treatment modalities.

From a treatment perspective, endovascular intervention is a rapidly evolving field with multiple choices and therapies available, especially with the evolution of drug-coated technology; however, with limited data in other aspects such as adjunctive therapy and a lack of established treatment algorithms and clear-cut guidelines, the inconsistency and variability in the field is a limiting factor. Unfortunately, from a treatment perspective, the devices and data for below-knee intervention are still subpar and the long-term results are far from satisfactory.

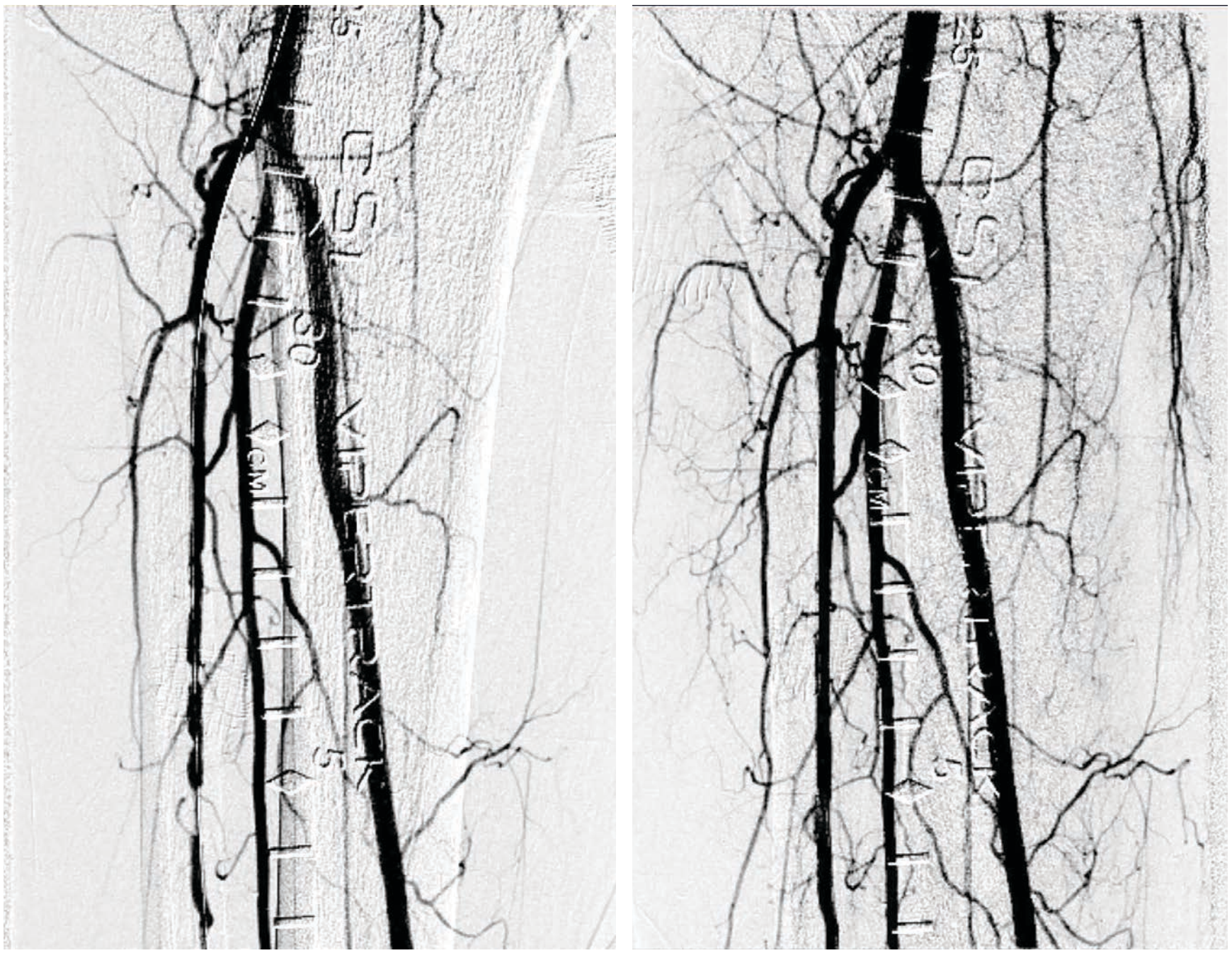


Figure 1. (Left panel) Stenosed infrapopliteal arteries in a patient with PAD. (Right panel) The same arteries after use of the Highlander™ 014 PTA Balloon Dilatation Catheter.

How do the anatomical challenges of below-knee intervention compare with above-knee intervention?

Above the knee, the vessels are larger in diameter and cross two hinge points (hip and the knee) while below-knee vessels are a smaller caliber. The problem for below-knee vessels is that there is no proven, effective, long-term definitive therapy. There are limited options such as atherectomy (for plaque modification) and balloon angioplasty, and sometimes the use of stenting (mainly in the proximal segment). Of course, there is the option of bypass surgery in some cases, but this can present its own challenges.

In other words, our hands are tied in regard to treating below the knee. Most of our patients will have diffuse disease extending all the way distally. The patency rate drops in relation to increases in lesion length, complexity, and calcification.

Can you share more about treatment options below the knee?

The Highlander™ 014 PTA Balloon Dilatation Catheter is a great balloon for below-knee intervention. Its low profile and deliverability are some of the features that make the use of the balloon very attractive to me.

In below-knee interventions, there are limited treatment options. As discussed above, the use of adjunctive therapy such as atherectomy for plaque modification can be utilized. Various modalities are available such as directional atherectomy, orbital atherectomy, laser atherectomy, or a combination of one or the other to try to achieve maximum luminal gain, even though the data are sparse. We also have been using therapies such as specialty balloons to cut into the lesions. Sometimes we use intravascular lithotripsy as well, which has proven to show improvement in long-term patency in this segment. Over the last year or so since it became available, we have been using a lot of the Highlander™ 014 PTA Balloon Dilatation Catheter (BD) for our angioplasties below the knee.

What has been your experience with the Highlander™ 014 PTA Balloon Dilatation Catheter?

We have been using the Highlander™ 014 PTA Balloon Dilatation Catheter since it came out in early 2023. It is a great balloon because of its deliverability, non-compliance, and ability to expand in a controlled, uniform manner. As interventionalists, when we use a balloon, one of the important factors is the deliverability and crossing profile of the balloon. In my experience with the Highlander™ 014 PTA Balloon, the deliverability has been great. The Highlander™ 014 PTA Balloon is a low-profile balloon that I find helps me to cross complex lesions with relative ease.

In vessels with multiple tandem lesions with segments of normal vessel, a differential balloon expansion can cause flow-limiting dissections. That is where the design of the Highlander™ 014 PTA Balloon becomes important. The balloon maintains highly precise sizing relative to its labeled diameter, even at inflation pressures up to 30 atmospheres. In my practice, I have found that the Highlander™ 014 PTA Balloon Dilatation Catheter works well in the type of non-focal lesions we typically see in our below-knee interventions, which is why we prefer it as one of our treatment modalities.

Can you describe the cases where you tend to use the Highlander™ 014 PTA Balloon Dilatation Catheter the most?

Since we are a referral center, we see a lot of complex cases. We typically find more diffuse lesions, and the idea is to prep the vessel to increase the patency and outflow. If it is a long, diffuse lesion with areas of abnormal and normal segments, the Highlander™ 014 PTA Balloon Dilatation Catheter has helped us to expand the lesion well, providing adequate pressure for expansion at the tightest area of the lesion, while at the same time causing minimal trauma to the normal segments. In expanding the lesion, we want to cause controlled, non-flow-limiting dissection and increase the luminal gain, thereby helping with the patency and other PAD symptoms the patient is suffering from, all the way from rest pain to wound healing.

Would you consider the Highlander™ 014 PTA Balloon Dilatation Catheter to be a workhorse balloon for your below-knee interventions?

View Dr. Kapur's article online:

Definitely, the Highlander™ 014 PTA Balloon Dilatation Catheter is a workhorse balloon for me. If there is a very calcified lesion, sometimes we might use adjunctive therapy such as atherectomy or intravascular lithotripsy followed by use of a Highlander™ 014 PTA Balloon Dilatation Catheter. In almost all of our below-knee cases, the Highlander™ 014 PTA Balloon Dilatation Catheter is one of my preferred balloons.

Do you have any advice for those operators who may be interested in trying the Highlander™ 014 PTA Balloon Dilatation Catheter?

If interested, one should contact their BD sales representative and get a few balloons to the lab to try and get a feel for how it works. It is always good to talk to friends/colleagues who have used the balloon and get their input. We have a close association with our local BD sales representatives and they provide great support on the device.

Any final thoughts?

The Highlander™ 014 PTA Balloon Dilatation Catheter is a great balloon for below-knee intervention. Its low profile and deliverability are some of the features that make the use of the balloon very attractive to me. Overall, in my practice, the Highlander™ 014 PTA Balloon Dilatation Catheter has performed very well and is true to expectations. ■

This article is sponsored by Becton, Dickinson and Company (BD). Dr. Kapur is a paid consultant of BD. See important Safety and Risk Information below.

Vishal Kapur, MD, FACC, FSCAI, RPVI

Director, Endovascular Intervention, Mount Sinai Morningside; Associate Professor, Division of Cardiology, Icahn School of Medicine at Mount Sinai; Associate Director, Endovascular Interventions, Mount Sinai Hospital, New York, New York