AN INTERVIEW WITH...

Peter Gloviczki, MD, FACS

How would you summarize the purpose of the Venous MEDCAC panel that took place in July 2016?

The purpose of the meeting was to convene a panel to advise the Centers for Medicare & Medicaid Services (CMS) on coverage determination for interventions used to treat chronic lower extremity venous disease.

What were your impressions of the composition of the panel?

You always want an unbiased panel focused on methodology and determination of the best evidence. Without a doubt, this was accomplished. However, this runs the risk that knowledge about the disease itself among the panel is average at best. This was clearly the case here, so it was difficult to agree with selection of the members. The voting panel consisted of a cardiologist chair and a heterogenous group of nine physicians and health care professionals. It included only one venous disease expert, a vascular surgeon. It was reassuring to know that based on epidemiologic data, at least two other members of the panel likely suffered from chronic venous disease, so they likely knew more about the disease than other members. There were two additional venous expert physicians on the panel, but they were nonvoting members. Because of the lack of disease-specific expertise on the panel, there was quite a bit of time spent during the discussion to explain what chronic venous disease is and what signs and symptoms these patients have.

What were your impressions of the data presented and discussed?

We heard invited presentations and a detailed report from the US Agency for Healthcare Research and Quality (AHRQ) on a systematic review and meta-analyses of chronic lower extremity disease treatments. The review was based on 103 studies published between 2000 and 2015. Based on seven observational studies and excluding several studies on venous duplex ultrasound (DUS) published before 2000, the review surprisingly concluded that none of the society guidelines could be supported because there was insufficient evidence that DUS should be used as the first-line diagnostic test for chronic venous disease. Those of us who were in the audience with the experience of having treated thousands of patients with the help of DUS during the past decades were wondering if we need a randomized controlled trial to prove that a parachute is needed when we jump out of a plane. The review of 84 randomized controlled trials also concluded that several endovenous interventional therapies have not been rigorously tested and that the presence of significant clinical heterogeneity of these results makes conclusions on clinical outcomes uncertain. The AHRQ report impressed the panel members and dominated the meeting, and the discussion was hardly affected by the subsequent public hearing of 4-minute expert presentations by society members, including the Society for Vascular Surgery (SVS)/American Venous Forum (AVF) coalition, the multiple society MEDCAC coalition of nine societies, and a representative of the AdvaMed medical industry coalition.

After the MEDCAC meeting, you expressed that although the panel's confidence in interventional management of lower extremity chronic venous disease was lower than expected, the SVS and AVF were optimistic overall. What are the reasons for this optimism?

I am optimistic that the MEDCAC vote will not slow the tremendous progress that has taken place in the field of minimally invasive endovenous interventions. The vote of 3.33 (intermediate to high confidence) to the question of whether there is sufficient evidence for an intervention that improves immediate/near-term health outcomes in patients presenting with symptoms was, in fact, quite close to the score of 4 recommended by the SVS/AVF coalition. Although the other votes were somewhat lower, they reflect the fact that most randomized studies and meta-analyses did not differentiate the Medicare population from younger

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patients. So, in the population MEDCAC is most interested in, data are indeed insufficient to provide a high level of evidence on efficacy. However, the message to me is not that new techniques don't work, but rather, we don't have enough data to support efficacy in the Medicare population. Thus, more data are needed, and these data should come from real-world experience in addition to randomized controlled trials. The SVS and AVF are already working on data collection in the prospective Vascular Quality Initiative registry.

What comes next in terms of timelines for decisions, if any?

I am hopeful that major changes will not occur in reimbursements. I also hope that the peer-reviewed society guidelines will be respected and reviewed by CMS, especially the most recent SVS/AVF venous ulcer guidelines that were omitted from the AHRQ review. Our society guidelines, both on varicose veins and venous ulcers, not only bring evidence that venous ablation should be the primary treatment for chronic venous disease and not compression stockings, as recommended by insurance companies, but it also reviews more meta-analyses and well-designed observational studies with long-term follow-up that the AHRQ report did not consider.

In which lower extremity clinical presentations do you prefer to employ surgical repair over percutaneous techniques?

Percutaneous techniques revolutionized the treatment of both superficial and deep venous disease. For treating superficial chronic venous disease, including varicose veins and chronic venous insufficiency, I use percutaneous radiofrequency ablation for saphenous vein ablation and open surgery for phlebectomy of varicose tributaries. High ligation and stripping is reserved for some patients with congenital varicose veins and some with aneurysmal saphenous vein close to the saphenofemoral junction. For chronic iliofemoral obstruction, I use percutaneous stenting if possible. If not possible or stenting fails, surgical bypass is a good and durable alternative.

What led to the creation of the SVS Interactive Practice Guidelines (SVS iPG) app? Is there anything that you would add to this app?

We are so pleased with the success of SVS iPG, the interactive practice guidelines app to treat peripheral arterial and venous diseases. The program is fully updated; it has 11 guidelines with simple access to evidence-based recommendations. It is useful for health care providers and also for patients seeking medical help for vascular disease. In addition, it is an educational tool for trainees and a source of information for third-party payors. This app is much more than a program that brings you the full PDF file of all SVS (and joint AVF) guidelines. It also has key information on each topic, an abstract, an explanation of the grade framework used to evaluate scientific evidence, and it gives you grades of recommendations. The app contains a summary of the individual guidelines and has different calculators to make documentation of the disease easier. The program will calculate the patient's CEAP score, the Villalta score for a patient with venous disease, or even the Wound, Ischemia, and foot Infection (WIfI) score for a patient with critical limb ischemia.

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As Chair of the SVS Document Oversight Committee at the time we launched this application, we wanted to have easy access to important guidelines to all vascular specialists. Nothing is easier than a few clicks on your smartphone or mobile device. Is there is anything we need to add to this app? The answer is yes, we need a search engine, and we are working on it.

Other than this app, what is your favorite medical app? And nonmedical?

I do most of my medical searches on the Mayo Clinic internal website and the Mayo Clinic library. Most recently, as Editor-in-Chief of the *Journal of Vascular Surgery* publications, I use the *Journal of Vascular Surgery* app and the SVS app. The nonmedical apps I use most are mail, iTunes, Kindle, Messages, Weather, CNN, Amazon, and My Delta.

What is your opinion on the potential utility of bioresorbable stents/scaffolds in lower extremity disease?

I love the idea of placing a device in the body that treats the obstruction but disappears when no longer needed. In-stent restenosis, development of a thick pseudointima, and late stent thrombosis of metal stents are problems, so I agree with those who believe that bioresorbable stents are the way of the future. I applaud the US Food and Drug Administration's decision to approve the first fully bioresorbable coronary stent earlier this summer that is supposed to completely disappear from the vessel after 3 years. Hopefully, this will allow approval of larger-diameter bioresorbable stents and scaffolds suitable to treat larger vessels. There is definitely a need to finally have dedicated stents for large veins. Return of vessel wall function and late restenosis of the bioresorbable stents are, of course, potential problems, and we may have to wait years to know more about them.

Your wife is an extremely talented visual artist and doctor. Are there ways in which venous treatment is like an art?

I love art, and it is an integral part of my life. I am so excited to see Monika's paintings as she creates them and then as the final products are displayed in our home or in a gallery (see her online gallery at www.art-mine.com/artist-page/monika_gloviczki.aspx). To me, medicine in general and venous disease treatment in particular is much more than application of advanced technology to treat a disease. Medicine is both science and art. As one of the great American poets and translator of Dante's *Divine Comedy*, John Ciardi once said, "When science touches man, it turns to art." ■

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