AN INTERVIEW WITH…

Kathleen Gibson, MD

Dr. Gibson provides updates on the efforts of the International Pelvic Venous Work Group, the SeCure and CREST-2 trials, and more.

Can you give us an update on the current efforts of the International Pelvic Venous Work Group and its goals for the near future? How did the international consensus meeting go last summer?

The International Pelvic Venous Work Group continues to make progress. Last July, the group met with a primary goal of developing a descriptive tool, much along the lines of the CEAP (clinical, etiology, anatomic, and pathophysiology) classification for lower extremity veins, for describing pelvic venous disorders. A draft of this instrument was developed and further refined at a second meeting at the American College of Phlebology (ACP) Annual Congress in Nashville, Tennessee, in November 2018. The goal of the group is to finalize this tool, with publication sometime in early to mid 2019. Simultaneously, work continues in developing validated disease-specific, health-related, quality-of-life outcome measures that can be used as a primary endpoint in clinical trials, including drug and device trials to support labeling indications.

What kind of involvement are you hoping for from those outside of the work group at this time, be it practitioners or industry?

The work group will primarily be financed via grants and funding from society foundations. Thus far, both the Society of Interventional Radiology Foundation and the American Vein and Lymphatic Society (the newly announced name for what was previously known as the American College of Phlebology) have supported this initiative. I would encourage any practitioners or interested industry colleagues to provide support to the foundations, which are going to be funding our efforts.

Can you provide some insights about the findings regarding the use of cyanoacrylate without compression stockings and any significance they might indicate about the role that compression should/should not play in venous disease treatment?

In terms of the use of cyanoacrylate closure without the use of compression stockings, our findings from the WAVES trial showed that we could achieve excellent closure rates and low rates of postoperative pain after treating incompetent saphenous veins without stockings. The mechanism of action of vein closure using adhesive does not require stockings to be effective. That being said, if a patient prefers wearing stockings, has wounds, or undergoes concomitant sclerotherapy or microphlebectomy, use of compression stockings may be beneficial. Although it is fairly standard by many practitioners to require the use of compression stockings after endothermal ablation, there is no strong evidence that it is necessary. Stocking use after endothermal ablation may be more of a tradition than an integral part of postprocedural recovery. My personal bias is that in patients undergoing sclerotherapy or phlebectomy, stockings can decrease bruising and discomfort. Compression stockings are of most benefit In the treatment of patients with more advanced venous disease, such as those with significant edema, skin changes, or history of ulceration.

What can you tell us about the SeCure trial's goals and progress to date?

Preliminary results of the SeCure trial, which is studying endovenous laser ablation, were first presented last November at the ACP Annual Congress, followed by several presentations the following week at the VEITHsymposium in New York City. The trial met its primary performance goals in terms of initial technical success and early closure rates. Additionally, there were statistically significant improvements in physician-derived

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severity scores and quality-of-life scores. As of this writing (December 2018), we have just finished collecting the 1-year data in all patients this past week. After these data are analyzed, we hope to submit the results for publication in early 2019.

Are you aware of any current or upcoming efforts to increase patient and referring physician awareness of pelvic congestion syndrome in women? What is the most important thing that each of these populations should know?

At this time, I am unaware of any formal patient or referring physician educational efforts on anything but a small scale in terms of pelvic venous reflux, although such efforts are needed. Outreach efforts will not only need to be made directly to patients but, importantly, to primary care doctors, gynecologists, urologists, and those in the pelvic pain community. Having "cross-pollination" of ideas between these stakeholders will be important. The venous community needs to be effective in communicating the role of venous disease in patient symptoms and in potential treatments, and the gynecology/pelvic pain community should in turn share their expertise in this area with physicians treating venous disease. For patients, the key message is to find or be referred to an expert in the area of pelvic venous disorders, so that appropriate diagnostic workup and treatment can be pursued.

What do you predict will be the net result of the current class of clinical trials in venous stenting? What will their effect on the field have been when looking back in 5 years?

I predict that several new venous stents will be approved and marketed in the United States as a result of the clinical trials. The trials will likely show good safety and efficacy, but whether or not these new stents will be better than our existing technologies will be unanswered without either comparative trials or registry data collection. Having more choices in the type of stents available for the treatment of venous disease over the next 5 years will be welcomed by those who treat venous obstruction. Their increased ease of use, however, could possibly lead to the overutilization of venous stents. Guidelines regarding which patients will most benefit from venous stenting, particularly among nonthrombotic patients, will be important.

How is the CREST-2 trial progressing thus far, and when do you envision results will be shared?

As of November 2018, the CREST-2 trial had enrolled more than 1,200 patients, so enrollment is about 50% completed. One of the challenges to study enrollment, at our site anyway, is that patients often do not like the idea of being randomized to either an intervention or medical management. Many patients have a strong opinion about whether they do or do not want to undergo intervention. Nonetheless, this is a critically important study that will hopefully be finished with enrollment in 2020, with results being shared after that time.

How might the data from CREST-2 affect the practice of carotid revascularization? What are the extremes of the spectrum?

The CREST-2 study may have a profound impact on whether carotid revascularization is offered to asymptomatic patients with high-grade stenosis. Although carotid revascularization is primarily performed to reduce the risk of stroke, the CREST-2 study is also investigating whether or not cognitive decline can be lessened by intervention. If so, these results could have an enormous impact on a potential new indication for treating carotid stenoses.

What is one item your colleagues might be surprised to learn is on your bucket list?

I traveled to Japan for this first time this year (twice) and fell in love with the beauty of the country and the culture. One of my bucket list items is to spend some time hiking in the countryside from *ryokan* (a Japanese country inn) to *ryokan*, either in the spring or fall. Also, I would love to learn how to speak Japanese! ■

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