

INTERVIEW

The SAVVE Trial: Assessing the Safety and Efficacy of the VenoValve Device for Deep Venous Reflux

An Interview with Cassius Iyad Ochoa Chaar, MD, MPH, MS

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Vascular Disease Management spoke with vascular surgeon Cassius Iyad Ochoa Chaar, MD, MPH, MS, from Yale New Haven Hospital in Connecticut, to discuss an abstract he presented at VAM25. Entitled “Patients With Deep Venous Reflux Continue to Experience Clinical Improvement 2 Years After Implantation of the VenoValve,” the presentation provided an overview of a prospective, multicenter trial that Dr Chaar and colleagues conducted, the Surgical Antireflux Venous Valve Endoprosthesis (SAVVE) trial, to assess the safety and efficacy of the VenoValve device (enVveno Medica Corporation). Dr Chaar talked about the study and how its findings can impact patient outcomes.

Tell us about the SAVVE trial. Why did you conduct the trial, what did it assess, how many participants, and how long will the trial last?

The SAVVE trial is a prospective industry-sponsored trial looking at the VenoValve, which is a bioprosthetic valve. It is a porcine aortic valve that is sutured on a metal frame. It is implanted in the femoral vein in the leg to treat patients with deep venous reflux who have incompetent valves in the deep veins and symptoms consistent with advanced venous insufficiency. These are patients with a CEAP score of C4 to C6 with the majority having venous ulcers. Currently, we do not have any surgical options for treatment of deep venous

reflux in these patients.

One of the inclusion criteria in the trial was that the patients do not have superficial venous reflux, which we typically treat with vein ablations, or have venous outflow obstruction or blockages in the iliac veins that we can treat with stents. These are patients with advanced venous disease and no surgical options, and the majority had ulcers on presentation, so they had the most advanced stages of venous disease.

The trial enrolled 75 patients in 21 centers around the United States. The results so far are very favorable. The follow-up is up to 5 years, and the data that I presented are for the majority of patients up to 2 years.

Your presentation dealt with the 2-year results of the trial. What specific improvements did you see, and where do you think the VenoValve fits into the current treatment landscape for patients with deep venous reflux?

The trial has shown that more than 80% of patients who were treated experienced clinically meaningful improvements in their venous clinical severity score (VCSS). Patients benefited significantly from that treatment, and those benefits were with respect to wound healing, pain scores, quality of life, and swelling. The benefit was noticed on various manifestations of venous disease. There was a 70% improvement in pain score and quality of life, measured by VEINES-SYM and QOL instruments. These patients are very challenging, and 75% of patients who had ulcers had them for more than 1 year. Those are patients we see in our clinics struggling with daily activities, and the only thing we can offer them is compression therapy or various forms of wound care. Now, we have a new treatment that can significantly improve their quality of life, their pain, and help get their ulcers to heal.

There is a significant proportion of patients who have venous reflux that we see in our practices where we do not have any options for them. Now we have a newer modality, which hopefully will be approved by the FDA, to help those patients improve their quality of life and improve their symptoms.

What are the next steps now that you have completed the 2-year follow-up?

We will continue following our patients and seeing if the VenoValve gets FDA approval. If it gets approved, there will be a lot of eligible patients who can benefit from it.

What is the main takeaway that you wanted attendees to get from your presentation?

The main takeaway is that there may be a treatment for patients with advanced venous disease and deep venous reflux in the near future. That treatment has shown beneficial results for 2 years, which is a good duration of time for patients with ulcers for several years. The hope is that these benefits remain and are sustained for a longer period of time.

These patients are typically a younger patient population compared to our traditional vascular disease patients who may have peripheral arterial disease or aneurysms. These are patients who are likely to live longer; gravity is really the enemy here. These patients are active, some of them work, some have daily commitments requiring them to be standing or walking, and we want to provide them with a treatment that lasts and helps them for a long period of time.

Is there anything else you would like to add?

This trial is a first step. There have been different techniques for repairing valves in open surgery without using a bioprosthesis, and those techniques have been limited to only a few centers worldwide that do a high volume with reportedly good results. But this experience has not been reproduced, and the learning curve for those procedures is steep, as best as I can tell. There are many different techniques that vary between centers, so there is no unification of the surgical technique to repair valves.

Having a bioprosthesis has not only been shown to be effective, but it also simplifies the procedure and makes it more reproducible and consistent between different centers. One can disseminate that treatment across centers and across the world. The complexity and variation in techniques of open valvular reconstruction have been a barrier to dissemination. I believe a simpler surgery using a prosthesis will standardize the technique and promote dissemination.

At the same time, understanding the disease and the future is to continue studying it because it is a challenging disease. We are relying on one device to replace many valves in the lower extremities. Whether one valve is sufficient, or maybe more than one valve is needed, remains to be seen. On the other hand, we do not know who are the patients that will benefit most from this valve. Those are questions that I do not have a good grasp on. Investment from companies, researchers, and potentially healthcare organizations and research funding bodies is needed to better understand deep venous reflux because it is a disease that affects a large proportion of people around the world. ■