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Colombian researchers report positive 24-month results for VenoValve

By **Bryan Kay** - 20th August 2021

Sebastian Cifuentes reveals 24-month data for VenoValve

Promising two-year results for an emerging potential prosthetic venous valve replacement—which is about to commence a U.S. pivotal trial—were announced at the Vascular Annual Meeting (VAM) in San Diego on Thursday afternoon.

Researchers from Bogota, Colombia, revealed that patients treated with the bioprosthetic VenoValve (Hancock Jaffe Laboratories) were found to have seen a 63% improvement in venous reflux time, 60% improvement in venous clinical severity score (VCSS) score, and a 93% improvement in their recorded pain when compared with preoperative levels.

The data were presented by Sebastian Cifuentes, MD, a vascular surgery research fellow at Fundacion Santa Fe-Universidad de los Andes, Bogota, Colombia during a VAM International Forum. Cifuentes is part of research team led by principal investigator Jorge Ulloa, MD, of the same institution.

Ulloa and colleagues recently published the six-month data of their first-in-human study of chronic venous insufficiency patients with C5-C6 disease in the *Journal of Vascular Surgery-Venous and Lymphatic Disorders*.

Eleven patients who were implanted with the device in Colombia completed one year of follow-up, with eight then followed out to 24 months. One patient died due to natural causes not related to the device, Cifuentes explained. “Another was not able to attend appointments due to age-related physical limitations, and we had one lost to follow-up.” Going forward, patients enrolled will be followed every six months for 48 months.

At 24 months after implantation, the research team found no device-related issues, Cifuentes continued. One patient

developed contralateral ulcers, he said, but neither hospitalizations nor recurrence of ipsilateral ulcers were noted. “Although wound healing was not our primary outcome, we have seen significant improvement in ipsilateral wound healing.”

The main two-year findings showed that venous reflux decreased from an average of 1.95 to an average of 0.72—a 63% improvement. “We can see that after 30 days of implantation, we have seen a stable improvement of the reflux,” Cifuentes elaborated.

Disease manifestations—measured by revised VCSS—decreased from an average of 13.38 to an average of 5.38, a 60% improvement. “This means we took patients from severe disease to mild disease,” Cifuentes said. Pain—measured by visual analog scale (VAS) scores—decreased from an average of 7.25 to an average of 0.5. This represented “a dramatic improvement, he added.

“These results allowed VenoValve to start a U.S. pivotal trial, the SAVVE [Surgical anti-reflux venous valve endoprosthesis],” Cifuentes explained. “Our results show that VenoValve appears to be safe. Our patients had a 63% improvement in reflux time, 60% improvement in VCSS score and a 93% improvement in their pain levels compared with preoperative levels. The VenoValve has shown a good safety profile, with few complications, and benefits that outweigh the known risks.”

The SAVVE US pivotal trial for the VenoValve will include 75 patients at up to 20 sites. The primary endpoints for the SAVVE trial will be the same as for the first-in-human trial: the primary safety endpoint is the occurrence of a major adverse event (MAE) in less than 10% of patients at 30 days post-VenoValve implantation, and the primary effectiveness endpoint is improvement of reflux equal to or greater than 30% at six months following VenoValve surgery. MAEs are defined as the composite of all-cause mortality, deep wound infection, major bleeding, ipsilateral deep vein thrombosis (DVT), or pulmonary embolism. Improvement of VCSS and visual analogue scale (VAS) scores are also included in the SAVVE study as secondary endpoints.

The Food and Drug Administration (FDA) recently granted Breakthrough Device designation status to the VenoValve.