First in Human Study for the Valiant Mona LSA Graft: An Interview With Frank R. Arko, MD

Interview by Jennifer Ford

Dr. Frank R. Arko is a vascular surgeon at Sanger Heart and Vascular Institute at Carolinas Medical Center in Charlotte, North Carolina. Dr. Arko reports consultancy to Medtronic.

The Valiant Mona LSA branch thoracic stent graft system (Medtronic) is the first device of its kind to undergo clinical evaluation in the United States. It demonstrated proof of concept in a first-in-human study being conducted under the US Food and Drug Administration (FDA) Innovation Pathway early feasibility pilot program. Data from the study was presented at the 2013 VEITHsymposium. Vascular Disease Management spoke with one of the study's investigators, Frank Arko, MD, about the study at the VEITHsymposium meeting.

Q: Please share a little more detail about the First in Human Study for the Valiant Mona LSA graft.

A: The study has recently been completed. We have 6-month follow-up for all of the patients. This is a study that has gone through the innovation pathway of the US Food and Drug Administration. I believe this is one of the first devices to be tested. It involved two centers. One was Carolinas Medical Center Sanger Heart and Vascular, where we performed the implants for 4 of the 7 patients. The other was The Cleveland Clinic, where they implanted grafts in the other 3 patients. Overall results of the study were quite encouraging and all the patients have done quite well. The results have yet to be presented. They're going to be presented soon by Eric Roselli, MD, a cardiothoracic surgeon at the Cleveland Clinic in Cleveland, Ohio.

Q: Can you share some of the more remarkable results?

A: The results have been very good and the investigators were focused on being able to implant the device successfully. We were able to do that in all 7 patients with really no major morbidities or mortalities. So the results were very good and will be very encouraging.

Q: What challenges could the use of the stent overcome for vascular specialists?

A: It allows you to revascularize the left subclavian in a straightforward, easy fashion. It basically removes

the need for doing a carotid subclavian bypass, and you can gain access through a brachial approach and then snare the wire, bring that branch up, and for the most part do everything right through the groin. Whether you do an open cut-down for the groin or you do that percutaneously — it can be done either way. The overall deployment is very easy, safe, and again it takes away the need for an incision in the superclavicular region for that subclavian carotid bypass.

Q: Have there been other data collected on the stent prior to this?

A: For this study, there have not. There were a large number of animal studies that were done that were part of getting this approved through the FDA innovation pathway, but no other studies in humans have been done as of yet.

Q: Are there any potential limitations to the device?

A: You know, there are some inclusion-exclusion criteria for it in the original first-in-human trial. The inclusion criteria were very strict for getting patients enrolled as part of this innovation pathway. The one key is that you do need a certain distance between that left carotid and left subclavian and you need space of around 1 cm to do that and you also need about a 5 mm neck just distal to the left subclavian. But other than that, the criteria for the standard Valiant Stent Graft is about the same so you can treat patients all the way up to a 42 mm neck length. We didn't limit the amount of angulation or anything like that up in the arch. So the main limiting factor is the distance between the left carotid and the left subclavian.

Q: Is there anything else you wanted to add about the graft and the first in human study?

A: I would add that overall it's a very safe procedure. The company has made a device that's very easy to use, very user-friendly. It's very accurate in its deployment, and the patients who I've treated so far have all been very happy with it and the results that we have seen all the way up to 6 months have all been very good. We used a very rigorous study in looking at the patients both preoperatively as well as postoperatively, looking at the aortic movement and the stent graft was really developed to be made to kind of accommodate the aorta rather than the aorta having to accommodate the device. ■