VDM Vascular Disease Management

INTERVIEW

PROMISE II, PROMISE I, and European 2-Year Registry Results With Deep Vein Arterialization Using the LimFlow Device for CLTI With Gangrene

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Keywords Critical Limb Threatening Ischemia

December 2023
ISSN 2152-4343

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VASCULAR DISEASE MANAGEMENT 2023;20(12):E229-E230

At the 2023 VEITH Symposium in New York City, Daniel Clair, MD, presented a session called “Pivotal US Trial (PROMISE II), US Feasibility Study (PROMISE I) And European 2-Year Registry Results With Deep Vein Arterialization Using the LimFlow Device For CLTI With Gangrene Shows Reasonable Limb Salvage and Wound Healing.” *Vascular Disease Management* spoke with Dr. Clair to discuss the registry results and what they mean for patients with critical limb-threatening ischemia (CLTI).

Dr. Clair, tell us about the PROMISE studies and what they were all about.

Both PROMISE studies, PROMISE I and PROMISE II, consisted of a single-arm treatment model. PROMISE 1 primarily served as a feasibility study in 32 patients, and it looked at venous arterialization using the LimFlow stent-graft system in patients with Rutherford Category 5-6; these patients had to have tissue loss in order to be enrolled and had to be independently adjudicated as not having a mechanism for standard arterial revascularization, either with an endovascular approach or an open surgical approach.

There were 3 sites in the United States; we expanded to 7 at the end of the study. Essentially, limb salvage at 6 months was just about 75%, and amputation-free survival was the primary endpoint of that trial, and it was above 70% in those initial patients.

How was the PROMISE II trial different from PROMISE I?

PROMISE II was an expansion of PROMISE I and, essentially, a pivotal trial for the technology, including an arterial crossover catheter, a venous Nitinol snare catheter to grasp the wire to allow through-and-through access and, purpose-built stents along with an integrated over-the-wire valvulotome.

The PROMISE II trial consisted of 105 patients enrolled at 20 sites. I was the co-principal investigator with Dr. Mehdi Shishehbor, and we looked at patients, again, who were independently adjudicated to have no revascularization option. They all underwent venous arterialization. The vast majority of those were done to the posterior tibial artery and vein, but some were done to the peroneal artery and vein. The success rate was nearly 100% technical success at the time of procedure, which was great because there were no roll-in patients, meaning that these may have been the first patients that any of these interventionists had tried to do venous arterialization in.

Also, PROMISE II included dialysis patients, who had been excluded from PROMISE I. That did, in fact, affect the outcomes. The 6-month amputation-free survival in that group of patients was just about 69%, and there was a clear difference between dialysis and nondialysis patients; that difference was not limb salvage but overall survival. And what I presented recently were 12-month data on PROMISE I and PROMISE II. Patients in both studies had about a 75% limb salvage rate and an amputation-free survival rate that

was about 63%. If you take out the dialysis patients, that's closer to between 65% and 70%. That shows, basically, that it's durable at least, up to a year in these patients; if you can get beyond those first 3 months and keep your limb, it's likely that you will be able to keep your limb.

The real issue is that this is a very sick group of patients; the mortality for dialysis patients in particular is somewhere on the order of 65% at 1 year. For nondialysis patients, there's still an overall mortality rate between 15% and 20%. I think limb salvage helps that, but it doesn't completely solve the problem for these patients.

What additional information did your presentation cover?

I also talked about a third arm of the study that consists of the European investigators, which is about another 30 patients. Again, they have a similar Rutherford Category and have been similarly adjudicated not to have revascularization options. Those results look a little bit better, and it's probably because the results of the European outcomes were a little bit better than what we saw in the US trial.

Is there one key fact that you wanted attendees to take away from your presentation?

Before patients are considered for amputation because they don't have adequate blood vessels in the foot to revascularize, before you move to amputation, deep vein arterialization using the LimFlow stent-graft system ought to be considered. I think we're going to find that this is another option for patients with CLTI instead of amputation. ■