VDM Vascular Disease Management

INTERVIEW

One-year Results from the LIFE-BTK Trial and 2-year Results From the SWING Trial

An Interview With Ramon L. Varcoe, MBBS, MS, PhD, MMed (ClinEpi)

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At the 2023 VEITH Symposium in New York City, Ramon L. Varcoe, MBBS, MS, PhD, MMed (ClinEpi), a vascular surgeon from Sydney, Australia, presented several sessions, including “Progress In and 1-Year Results of the LIFE-BTK Randomized Controlled Comparison of Abbott’s Esprit Drug-Eluting Resorbable Stent With Plain Balloon Angioplasty (POBA)” and “Two-Year Results With the Sundance DCB (Surmodics) to Treat BTK Occlusive Lesions: From the SWING Trial.” Vascular Disease Management spoke with Prof. Varcoe about these 2 trials and what the current results mean for patients with peripheral arterial disease (PAD).

Prof. Varcoe, why are these 2 studies important for patients with PAD?

These studies are all about this global epidemic of PAD—230 million people around the world are suffering from this inflammatory disease, and those with critical limb ischemia (CLI), which is the most severe manifestation, are at high risk of limb loss. We all know how devastating amputation is to quality of life, but CLI has a prognosis worse than most cancers, which many people don't understand. If we can save these limbs, we’re doing the world a huge service. If we look at the patterns of arterial disease that contribute to limb loss, they almost always involve some degree of below-the-knee (BTK) or infrapopliteal atherosclerotic disease. The trials I've been speaking about at here at VEITH are both associated with the treatment of infrapopliteal disease; the first trial was called LIFE-BTK.

Tell us about the LIFE-BTK trial, which compared the Esprit drug-eluting stent with plain balloon angioplasty.

The results were published in the New England Journal of Medicine on October, 25, 2023, and simultaneously presented at the TCT conference. LIFE-BTK is a large global prospective randomized controlled trial that was designed to evaluate a novel bioresorbable drug-eluting scaffold called Esprit BTK (Abbott). We used the scaffold for lesions in the proximal two-thirds of the calf. We randomized 261 patients and it was a 2-to-1 randomization, the 2 being Esprit and the 1 being angioplasty, and we followed these patients for 12 months. There were several endpoints, but the most important were the 2 primary endpoints: a primary efficacy endpoint and a primary safety endpoint. The primary efficacy endpoint was a composite of freedom from major amputation, clinically driven target lesion revascularization, target vessel occlusion, and a binary stenosis.

The safety endpoint was freedom from major adverse limb events and perioperative death in 6 months. Here at VEITH, I presented the data at 12 months for the primary efficacy endpoint, which was quite remarkable. We saw that the scaffold arm of the study truly outperformed angioplasty. The risk difference at the end of that 12-month period was 30.8%, which is highly statistically significant and shows clear superiority of the scaffold over angioplasty. To put that into context, it’s the first drug-eluting resorbable scaffold that’s ever been shown to be effective BTK in a randomized controlled trial with this sort of rigor. But it's also the only drug-eluting device of any kind that's been shown to be effective BTK in a large-scale, randomized controlled trial like this. These remarkable

findings are meaningful because at the moment, the only approved product for BTK interventions in the United States is angioplasty for primary therapy. So if Esprit BTK is approved, it could well give us another tool in our toolkit that's going to improve outcomes for patients.

What about the SWING study? What did that look at, and what have the 2-year results shown?

The SWING study looked at Sundance (Surmodics), a novel drug-coated balloon (DCB). Rather than paclitaxel, which has been commonly used in the past, this DCB uses sirolimus, which is a bit different than paclitaxel. It's been used for decades on coronary stents, and we know it's safe and seems to be better suited to BTK applications than paclitaxel, as all the paclitaxel-coated balloon trials have failed. Other aspects of this technology are really interesting—the DCB has a novel way of coating the balloon with these micro-pipettes that provide a microcrystalline structure on the surface of the balloon. It looks different to the naked eye, quite white and opaque, but it also looks different under scanning electron microscopy, where it's very uniform and has a truly microcrystalline structure.

So we used the Sundance DCB in an early feasibility study over 3 regions: Australia, New Zealand, and Europe. There were 35 patients in total over 8 sites who we followed for 24 months. What we found was that in the per protocol arm of the study, there was a primary patency of 71% at 24 months, which is really very good. It's consistent with what we saw earlier in our 6-month follow-up, because the 6-month follow-up was an angiogram. We saw excellent luminal gain in that angiogram and limited late lumen loss, which tells us now, at 24 months, that the signal toward efficacy has been proven to be sustained and, very pleasingly, also safe. We've seen almost no major adverse events. This is an early study of a novel device, but it gives us great encouragement and optimism and we'd like to see it now evaluated in a large-scale pivotal trial.

What do these studies tell us about the future of PAD treatment?

Very few new tools have come along in the BTK space for too many years now. We've been doing simple angioplasty, and as we know, it has limitations. It has no mechanical support, has no anti-stenotic properties, and you see immediate failures because of the lack of mechanical support. Then you see late failures because of restenosis. What that means in practical terms is patients either suffer recurrent CLI, their symptoms worsen and possibly require amputation, or they have to have repeat reinterventions, with all the risk and cost that comes with that. We all know there's risk with every reintervention. We think that these new tools give new hope for those complex patients and the industry, which has seen a series of failed BTK trials. Industry was looking very closely at the LIFE-BTK trial, in particular, to see whether it would be successful, and they can now use that trial design methodology as a template for new trials moving forward. ■

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