**Title: Unplanned Limb Revascularization with Rivaroxaban in Patients with CLTI After Endovascular and Surgical Treatment**

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**Dr Shea Hogan**

"Hi, my name is Shea Hogan. I'm an interventional cardiologist and vascular medicine specialist at Denver Health Hospital in Denver, Colorado. I'm also an associate professor of clinical medicine in the University of Colorado School of Medicine and a clinician scientist at CPC Clinical Research, which is an academic research organisation affiliated with the University of Colorado.

**What are the current treatment options for patients with CLTI?**

So currently, the main strategies for CLTI include revascularization, which may be either a surgical approach, an endovascular approach, or a hybrid approach in which both surgery is done usually on the common femoral artery, and oftentimes the endovascular approaches below the infrainguinal arteries, as well as, obviously, risk factor modification and medical management, including antiplatelet therapy, antithrombotic therapy, statin therapy and lipid lowering therapy.

**What research questions have arisen from the publication of VOYAGER-PAD, BEST-CLI and BASIL-2?**

Well, it's nice that we're finally getting some randomised controlled data in this space. Historically critical limb threatening ischemia has been kind of under recognised and understudied, even though it's a very severe condition that has high morbidity. And so it's great that we're finally looking at these patients and asking these questions about what management strategies are superior.

CLI helped us with the question of is surgical approach or an endovascular approach superior in this patient population? I think the results were not surprising to most of us who work in this space, in that in patients who can have either approach, if you have your own vein graft that can be used, you're probably gonna have a more durable outcome than an endovascular approach. But at the same time, a lot of these patients are very sick, they have a lot of comorbidities, and so many patients don't qualify for either approach. And most patients end up getting an endovascular strategy simply because they're too sick to undergo surgery.

In terms of, you know BASIL two, the question of infrainguinal disease is an important one, because we know that these patients do the worst if they have tibial disease. It can be very hard to have long lasting results from an endovascular approach. But in basal two, what we found was that actually an endovascular approach was superior, and that was actually driven mostly by mortality benefit. I think these trials help us understand that our endovascular therapies are becoming better and better, and that we now have a pretty competitive strategy either way. But obviously the most important thing is talking to your patients, evaluating them for surgery. If that's a possibility, then great, you can discuss that with them. But if not, then an endovascular approach will help.

One question that comes up with these patients a lot is repeat interventions. And as I mentioned, these patients are very sick. They tend to have a lot of comorbidities, as I've mentioned, and they spend a lot of time in the hospital. And so having to undergo repeated revascularization becomes a big deal because patients spend time in the hospital. That's money spent. That's time spent. Complications can occur from these procedures. We really want to try to minimise the amount of procedures that they have to undergo to heal their wounds and salvage their legs.

**What were your key findings, and take-home messages for clinicians?**

The question in our study was, rivaroxaban has been shown to improve major adverse cardiovascular events and limb events, and patients with Pad who undergo lower extremity revascularization. But the question that we posed was, well, in the sickest population, the CLTI group, was there a difference in effect on rivaroxaban in the surgical versus the endovascular approach? What we found was that both groups derive benefit from rivaroxaban. We know that whether you have surgery or whether you have endovascular approach, if you're in the sickest population, you do have benefit on low-dose rivaroxaban. Well, I think one is that in any patient who's undergone a lower extremity revascularization, no matter how sick they are, if they're not at high risk for bleeding, that you really should be thinking about low dose rivaroxaban in addition to single antiplatelet therapy in this population, because patients, they'll derive both a cardiovascular and a limb benefit. Many times when we think of the sickest patients, we say, oh, maybe they're going to bleed and have issues from that standpoint. But I think the data continues to show that even though these patients are sick, they do derive benefit. That's a great question.

**What further study is needed?**

I think learning more about why patients progress from peripheral artery disease that affects them when they walk to the most severe stages of peripheral artery disease. I think that is a critically important question, because if we can identify which patients are going to do this, then hopefully we can come up with therapies to modify that projection for their disease. I also think, obviously, new strategies, new medical therapies and new equipment to be used in the endovascular space to try to help these patients, because the end result of CLTI is often limb loss, major limb loss. And that's really devastating to patients. And it's also very costly from both a human value standpoint, from a time standpoint, as well as a financial standpoint. So I think, you know, developing more management strategies in this space and identifying these patients earlier on are both very critical for research moving forward.”