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ACC 2024: VOYAGER PAD Part 1

Announcer:

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Dr. Bonaca:

My name is Mark Bonaca. I am a cardiologist and a vascular medicine specialist at University of Colorado School of Medicine, and I'll be discussing 2 abstracts from the American College of Cardiology Meeting 2024. Both of these analyses were performed focused on patients with peripheral artery disease [PAD]. And by way of background, patients with peripheral artery disease suffer from high risk of things like heart attacks and strokes, but the greatest risk is of morbidity in the limbs, functional limitation, and amputation.

So we did 2 analyses that were really focused on ways of identifying which patients with peripheral artery disease are at highest risk of having these adverse limb events. We used a data set called VOYAGER PAD.

VOYAGER PAD enrolled over 6,000 patients with symptomatic PAD, some with critical and threatening ischemia, and randomized them to rivaroxaban or placebo and a background of aspirin. Demonstrated that rivaroxaban reduced major adverse limb events and, although it increased bleeding, there was an overall net benefit.

So in the first of these analyses, we looked at 2 scoring systems, one called the Rutherford scoring system, which is one that's been around for a long time, and then another one called WIfI [Wound Ischemia foot Infection], a more recent one developed by the Society of Vascular Surgery for patients with chronic limb-threatening ischemia. And we looked at how these established risk scores predict the risk of amputation.

And for this analysis, we looked at both major amputations, so ones above the ankle, and minor amputations, including the forefoot. And we looked at the risk over about 3 years.

And we found that, overall, the Rutherford classification system actually predicted amputation risk very well, and Wlfl predicted risk very well. And there was a graded risk of amputation with each increase in Wlfl or Rutherford. What was interesting, though, is we noted that neither score pulled in patient characteristics. So the novelty of this analysis is that we looked, then, at whether diabetes added new information, and it did. In fact, when we stratified the Wlfl score by diabetes, we found that it enhanced a whole category of risk, meaning it shifted people up in risk and it allowed better discrimination. And so we proposed, as a conclusion of this analysis, that maybe Wlfl should be called DM, or diabetes mellitus, Wlfl.

Now, the second analysis used the same data set, and it asked a similar question. How can we tell, as clinicians, which patients with peripheral artery disease have the highest risk of having an amputation or an acute limb ischemic event? But here, we used a different tool. Rather than risk stratification with risk scores, like Rutherford or Wlfl, we used anatomy. And we leveraged the VOYAGER PAD angiographic core lab where we have over 1,600 patients, core lab-read angiography, looking at multiple segments and multiple factors. And here, we said we want to know whether people who have disease below the knee are higher risk for major adverse limb events than patients who don't have disease below the knee. And so we were able to ascertain the number of patients who have below-knee

disease, and in the data set, we found that there were about 850 patients with below-knee disease and about 600 without.

We found that patients with below-knee disease were sicker than those that didn't have below-knee disease. They were more likely to have chronic limb-threatening ischemia, chronic kidney disease, older age, prior amputation, and so on. Although we didn't see a difference in diabetes, which was quite interesting. Then we looked at outcomes over 3 years, and we found that major adverse limb events were significantly higher in those with below-knee disease than those without below-knee disease. Patients with below-knee disease also seem to have higher rates of adverse cardiovascular events and mortality, but those were not statistically significant. And really, the difference in risk was driven by amputation, both minor and major, and acute limb ischemia.

And so what we've learned is that there are anatomic correlates of prognosis, even in patients after successful revascularization, like in VOYAGER PAD. And I think the take-home from these 2 novel abstracts is that we have a long way to go in terms of the sophistication for risk stratification in patients with PAD. They are quite heterogeneous in terms of risk. But DM-WlfI, using diabetes and the WlfI score and anatomy, knowing whether a patient has below-knee or above-knee disease, are 2 potent factors that we can consider now as we look at patients and assess their risk.

Thank you.

Announcer:

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