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Consistent Benefit of Rivaroxaban Early and Late After Lower Extremity Revascularization

Announcer:
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Dr. Bonaca:
Hi. My name is Marc Bonaca from the University of Colorado, and I'll be presenting the consistent benefit of rivaroxaban, early and late after lower extremity revascularization.

VOYAGER-PAD established the efficacy and safety in the overall favorable benefit risk for rivaroxaban after revascularization for symptomatic PAD. But there have been questions in translation. How early should we start? What if we're using DAPT? Is there a benefit early? And is the benefit consistent late? And that was the prespecified analysis that we looked at here and was the objective of what I'm going to show you.

I'm going to go straight to the key findings of the analysis. Here, we looked at the VOYAGER-PAD study. And we looked at the first 90 days on the left, and then from day 91 on to 3 years on the right. And we looked at the primary endpoint at the top, and then the principal safety outcome on the bottom, which you can see is in the first 90 days that there was a benefit. It was consistent. The hazard ratio was 0.78. And there was more bleeding but a net benefit. And when you look at absolute risk increase and decrease of over twofold that favorable benefit-risk ratio early. And that there was also benefit late there, and we saw consistency there as well. And so the benefit-risk in the profile were consistent early and late for the primary endpoint. Another way to look at this is to combine it as a net clinical benefit. So combining efficacy and safety. And here we see the same thing, that there's a 25% reduction in net clinical benefit, including bleeding, that's statistically significant on the right, as well as a significant benefit from 3 months on through 3 years. So consistent efficacy, consistent safety, and consistent net benefit for this strategy, both early and late.

Now, the real issue though, early, is what happens for those procedural complications or bad things like stent thrombosis of the leg, the acute limb ischemia, or major amputation. So we want to focus on that, specifically. And here on the left side of the slide, you see that the rate of adverse limb events is high in patients getting aspirin and statins and clopidogrel and many of them, and that the addition of rivaroxaban provides a benefit, the curve separates within just a couple of days, and that there's a 45% reduction in major adverse limb events. So rivaroxaban has a clear benefit early, it's also beneficial late, but perhaps even a trend towards a better benefit early. Then we focus on acute limb ischemia, that stent thrombosis of the limb, it's particularly prominent here on the left side of the slide, that early separation and overall 1% absolute risk reduction in 90 days, more than a 50% reduction in acute limb ischemia.

Now much of the question around this has been, what about DAPT? And if I'm using DAPT, is there a benefit early? And what's the benefit risk look like? We know there's more bleeding with prolonged DAPT, but shouldn't wait to start rivaroxaban? Here's the natural history of adverse limb events in patients getting aspirin, clopidogrel, and statins after revascularization. And you can see the event

rates are quite high. They're about 1.5 to 2% or even higher for really bad heart outcomes. And this looks like this old stent thrombosis literature after coronary intervention. And what this tells you is DAPT is not enough. Now when we look at the benefit of rivaroxaban on top of DAPT and statins, you can see that there's more than a 50% reduction in acute limb ischemia, and that stent thrombosis of the legs, as well as the composite of acute limb ischemia or major amputation. What this tells us is adding rivaroxaban early regardless of whether you're using DAPT, is really important to protect from major adverse limb events.

Now we did, on this slide, a forest plot. It's a lot of data, but what it means is if the point estimates are the left to the line, rivaroxaban is better, and to the right placebo is better. And no matter how you cut the data, 30 days, at 90 days, with or without clopidogrel, the primary composite or the limb outcomes, the story in the message are the same. The benefit is consistent early and late, that you should start early and continue long term.

So in summary, after lower extremity revascularization, rivaroxaban added to antiplatelet therapy reduces MACE and MALE, and increases bleeding but there's a favorable benefit-risk profile, and that is present both early and late. The reality is that rates of acute limb ischemia and major amputation are high after lower extremity revascularization, particularly early despite use of aspirin, statins, and clopidogrel. When you add rivaroxaban when it started within just a couple of days of the procedure, you can lower this risk by 50% or more. So this data, along with other datasets show that major adverse limb events after revascularization are a big problem, that the existing medications we've tended to rely on are not enough, that adding rivaroxaban reduces these events early and late on top of DAPT, and also extends into chronic PAD when we look at the COMPASS trial and the benefit for mortality and amputation. And so, in conclusion, in eligible patients with symptomatic PAD after lower extremity revascularization, rivaroxaban 2.5 milligrams twice daily should be considered and started early regardless of DAPT.

Thank you.

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