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ACC 2024: VOYAGER PAD Part 2

Announcer:
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Dr. Bonaca
Hi, my name is Mark Bonaca. I'm a cardiologist and vascular medicine specialist at the University of Colorado, and I'll be discussing 2 abstracts from the American College of Cardiology Meeting 2024.

We're looking, in these 2 abstracts, at the risks and different treatments for patients with symptomatic peripheral artery disease, and we chose a data set for both of these called the VOYAGER PAD randomized clinical trial, a trial that randomized over 6,500 patients with symptomatic peripheral artery disease to rivaroxaban plus aspirin or rivaroxaban alone, and demonstrated that rivaroxaban reduced the risk of irreversible harm events of the heart, limb, and brain, increased bleeding, but with a 6:1 benefit-risk ratio, and it is now approved for patients with PAD, the first drug ever to have an indication for preventing adverse limb events.

So the first question we asked was, was the risk profile and the benefit consistent among some of the key subgroups? And the first subgroup that we did for this analysis were patients who were smoking. We know that patients who smoke are at high risk of developing PAD and have generally worse outcomes. And so we looked in VOYAGER PAD. There were over 2,000 patients who were current smokers out of the data set, more than a third. And as you might imagine, patients who smoked were different than patients who didn't smoke.

In general, though, often seen with the smokers' paradox, is that patients who smoked were younger and had fewer comorbidities, meaning they had presented earlier with PAD. The next thing we looked at is how they did in the trial. And we looked at an endpoint called hospitalizations for any thrombotic coronary or peripheral event, something that happens very frequently. And we found that patients who smoked were at about a 20% to 30% increased risk for being hospitalized for a coronary or peripheral event, despite being younger and having fewer risk factors. And that suggests that maybe smoking is playing a role there, which is intuitive.

The second question that we asked was, were the benefits of rivaroxaban and the safety of rivaroxaban consistent between the 2 groups? And we found the same thing, actually. We found that patients who were smoking or nonsmoking each had a reduction of about 28% in hospitalizations. But because of the higher risk of the smoking patients, the number needed to treat was actually lower at 32, so they had a greater absolute benefit. But there was a robust reduction in those events whether you smoked or you didn't smoke.

The next thing we looked at was safety, and we found that the bleeding risk was consistent in the 2 arms.

Now, the next thing we looked at were treatments in patients with PAD. We used the same VOYAGER PAD data set, and we looked at those patients who received clopidogrel and who didn't, and we tried to see what's clopidogrel actually doing? That's the 800-pound gorilla when we talk about endovascular treatment for patients with PAD, does DAPT [dual antiplatelet therapy] have a benefit? And Connie Hess presented an abstract that propensity score-adjusted between the patients who got DAPT and didn't. Interestingly, before we adjusted, because it was nonrandomized, it appeared that there was lower rates of NACE and MALE [major adverse limb events] in

patients who got DAPT than did not, and not much of a bleeding excess.

Of course, this is because it's nonrandomized. And so when the groups were matched by propensity score, we found there appeared to be no benefit of dual antiplatelet therapy after endovascular revascularization, but there was about a 70% increase in bleeding. And then we looked amongst different types of ischemic events, and we found that the hazard ratio for the primary endpoint was 0.96. No benefit for DAPT. Now, you have to remember that this was a nonrandomized comparison, but with over 3,000 patients, this is one of the largest data sets exposed to DAPT that we have, and we have a large endovascular subgroup here.

So when we put the results of VOYAGER in context with other studies, we know that CASPAR showed no benefit of DAPT in bypass patients, CHARISMA showed no benefit of DAPT in chronic PAD, and although MIRROR was a very small trial, it suggested a benefit, but now in VOYAGER we have a very large data set, adjusted analyses, propensity score adjusted, and there does not appear to be any benefit of dual antiplatelet therapy, but increased bleeding risk.

Thank you very much.

Announcer:
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