Transcript Details

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Rivaroxaban Reduces Hospitalizations for Thromboembolic Events in Patients with Peripheral Artery Disease After Revascularization in Those With and Without Chronic Kidney Disease

Dr. Svet:
Hello, my name is Mark Svet. I'm a second-year resident at the University of Colorado. I'm presenting this on behalf of the Voyager investigators. It's titled: Rivaroxaban Reduces Hospitalizations for Thromboembolic Events in Patients with Peripheral Artery Disease After Revascularization in Those with and Without Chronic Kidney Disease.

There's currently an excess of 200 million adults worldwide affected by peripheral artery disease. Chronic kidney disease is an important comorbidity that often coexist with PAD. This is an important distinction to make, as individuals with renal impairment are also more likely to have worse outcomes, particularly vascular outcomes after lower extremity revascularization, but what's is an often underappreciated, and under-reported outcome, is that this patient group is also high risk for readmission following revascularization. In one study, six months after an index revascularization, 61% of those with CPD had been readmitted compared to 43% for those without. However, in 2020, the Voyager PAD trial, whose methodology is shown in the figure on the left, randomized approximately 6,500 patients with PAD to Rivaroxaban, two and a half milligrams twice daily on top of low dose aspirin versus aspirin alone in individuals following lower extremity revascularization. This showed that Rivaroxaban reduced the primary efficacy, and positive of irreversible harm to the brain, heart or limb, with an absolute risk reduction of 2.6% in a number needed to treat of 39. This represented a major step forward in the treatment of PAD.

However, there are a number of other outcomes where the efficacy of Rivaroxaban remains unknown. The topic of this presentation will focus on rates of readmission. This is clinically important because individuals with CKD have previously been shown to have higher rates of bleeding following revascularization. Add to this now, the routine use of Rivaroxaban, which is renally cleared, and individuals with renal impairment may be at even greater risk for bleeding events. This therefore represents a difficult clinical decision to balance the efficacy of anticoagulation against the risk of increased bleeding. Here, we assess whether the efficacy and safety of Rivaroxaban at reducing readmissions, particularly admissions of a thrombotic nature, was modulated by the presence of chronic kidney disease within the Voyager PAD trial. To this end, our key efficacy outcome was hospitalization for coronary or peripheral event of a thrombotic nature. This was a pre-specified secondary outcome. Our principle safety outcome, TIMI major bleeding, and we used Kaplan Meier estimates for the cumulative incidence of each pre-specified outcome.

Presented here are baseline characteristics. Baseline eGFR was available for approximately 6,300 patients of whom 21% had chronic kidney disease, which we define as an eGFR of less than 60. The mean eGFR among this group was 48. Within each subgroup, you'll see that randomization worked, and all P values were greater than 0.05. Drawing your attention to the purple columns however, you'll notice individuals with CKD were higher risk for cardiovascular events, as you would expect. They were older, had a higher prevalence of coronary risk factors such as hypertension and diabetes. Smoking however, was more common among those without CKD. Index ABI and rates of prior limb revascularization were similar.

Here are the primary results of the overall analysis. Starting on the left are the results for the overall cohort. You'll notice among this group, the frequency of readmissions for a thrombotic event was reduced with Rivaroxaban, as compared with a placebo. This had an

absolute risk reduction of 3.4%, and a number needed treat of 29. This effect was consistent regardless of the presence of CKD with a P for interaction of 0.25. Now looking at the you other plots, you'll see the data stratified by a CKD. Those with CKD had an higher absolute risk reduction and lower number needed to treat, with an absolute risk reduction of 4.7%, and a corresponding number needed to treat of 22. Whereas those without CKD had an absolute risk reduction of 3%, and a number needed to treat of 33. With efficacy established, we also looked at safety data. The findings for bleeding looked very similar to the whole trial overall. The primary safety outcome, TIMI major bleeding occurred more often in those treated with Rivaroxaban. However, this effect was consistent regardless of the presence of CKD with a P for interaction of 0.38. Among CKD patients, this represents an absolute risk increase of 1.4% in a number needed to harm of 71 for TIMI major bleeding. Also, important to note is there was no increased intercranial hemorrhage or fatal bleeding with Rivaroxaban in patients with or without CKD.

What this amounts to is that in a cohort of a thousand patients with CKD and peripheral artery disease, treatment with Rivaroxaban would prevent 47 readmissions related to thrombosis of a coronary or peripheral nature, as compared to 33, for those without CKD. Then looking at harm of Rivaroxaban in the same cohort would cost 14 TIMI major bleeds in those with CKD, as compared to nine events for those without CKD, but no intracranial hemorrhage or fatal bleeding events.

Ultimately, I think there are a few main takeaways from our research. A strategy of Rivaroxaban, two and a half milligrams twice daily plus aspirin versus aspirin alone, reduces hospitalizations for thrombotic events of a coronary or peripheral nature in patients with recent lower extremity revascularization. There's a higher absolute benefit with this strategy among those with CKD, compared to those without CKD. And although patients with CKD are at higher bleeding risk, overall, the bleeding risk with Rivaroxaban was similar in patients with or without CKD and should not cause clinicians to undertreat peripheral artery disease, as Rivaroxaban demonstrated net clinical benefit for reducing hospitalizations among the sub. Thank you for your attention.