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Rivaroxaban to Reduce the Risk of Major Venous and Arterial Thrombotic Events, Hospitalization and Death in Medically Ill Outpatients with COVID-19: Primary Results of the PREVENT-HD Randomized Clinical Trial

Announcer:
Welcome to CME on ReachMD. This episode is part of our MinuteCME curriculum.

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Dr. Piazza:
Hi, my name's Dr. Gregory Piazza, and I'm one of the vascular cardiologists at Brigham and Women's Hospital. And on behalf of the Prevent HD co-investigators, I'm thrilled to share with you the results of our study focused on Rivaroxaban to reduce the risk of major venous and arterial thrombotic events, hospitalization, and death in medically ill outpatients with COVID-19.

So, let's go back to the spring of 2020 in order to understand the rationale behind the study. Hospitalized COVID-19 patients were recommended to receive thromboprophylaxis as acute medically ill patients per ACC, ACCP, WHO, and ISTH guidelines. Rivaroxaban was approved in the US for thromboprophylaxis in hospitalized acute medically ill patients who are at increased risk for VTE, but low risk for bleeding. The D-dimer in COVID-19 was identified as an important marker of a procoagulant state and a risk factor for VTE, clinical deterioration, and death. Despite focus on hospitalized patients, the majority of patients with COVID-19 were being treated as outpatients. Outpatients with COVID-19 were suspected to be at risk for venous and arterial thrombotic events, especially in the setting of risk factors. And then finally, histopathological evidence suggested that at least part of the deterioration in lung function leading to hospitalization may be due to in situ pulmonary artery thrombosis.

Prevent HD was designed as a randomized double-blind placebo-controlled event-driven study. It focused on symptomatic patients with positive COVID-19 testing. They could be enrolled within 14 days of symptom onset, and they were randomized to Rivaroxaban 10 milligrams once daily versus an oral matched placebo, and then followed either by telehealth visit or web-based visit over the course of 49 days. Now, the study was stopped early due to a lower-than-expected event rate.

And here we see the primary efficacy outcome analysis. We enrolled 1,284 patients and randomized them to either Rivaroxaban or placebo. And we can see in the intention to treat analysis that there was no observed difference in the primary composite of any thrombotic event all cause hospitalization and death. Now, if you look at the modified intention to treat analysis, you'll see that the directionality changed, although there was still no significant difference, and that was due to the fact that a higher numeric proportion of patients did not receive study drug before being hospitalized in the Rivaroxaban group.

Now, additional analyses using the intention to treat set demonstrated no significant difference in a composite of symptomatic VTE and arterial thrombotic events and all-cause mortality. But we did find in a post hoc exploratory analysis a reduction in symptomatic VTE and arterial thrombotic events in patients receiving Rivaroxaban

For safety outcomes, our primary or principal safety outcome of concern was fatal and critical site bleeding. We didn't observe any fatal or critical site bleeds in either population. There was no significant difference in ISTH major bleeding, and we observed a significant but

modest increase in non-major, clinically relevant bleeding in patients receiving Rivaroxaban.

So, to summarize, Rivaroxaban prescribed for 35 days in non-hospitalized patients with symptomatic COVID-19 at risk for thrombosis was not found to reduce a composite endpoint of venous and arterial thrombotic events hospitalization and death. And this is in line with prior studies that also looked at an outpatient population. With all the caveats of a post hoc exploratory analysis, we did show a significant reduction in venous and arterial thrombotic events. Bleeding overall was low and generally consistent with the known safety profile of Rivaroxaban at a thrombo prophylactic dose and with the caveat that the trial was under power to provide a definitive conclusion, these data do not support routine antithrombotic prophylaxis in non-hospitalized patients with symptomatic COVID-19. And with that, I thank you and I want to thank all of my co-investigators and the team that helped to make Prevent HD a reality. Thank you.

Announcer:
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