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ACC 2024: The PIONEER AF-PCI Trial

Announcer:

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Dr. Patel:

Hi. My name is Manesh Patel. I'm a cardiologist at Duke University, and this is Duke Heart On The Go conference coverage from the American College of Cardiology, 2024. Lots of great science at the meeting and I thought I'd give you guys a couple of updates on some important studies and abstracts that we saw.

One of them that I thought was important is just another, sort of, substudy or description from the PIONEER-AF study. Reminding you all that the PIONEER-AF study is a study evaluating patients with atrial fibrillation undergoing PCI [percutaneous coronary intervention]. And this abstract looked to see how patients undergoing that PCI, who got rivaroxaban versus warfarin, which was the design of the study, did on the elderly patients. Because, you know, as we go into clinical practice, more and more of our elderly patients undergo PCI, and one of the questions is, you know, how safe and efficacious are some of these DOACS [direct oral anticoagulants] when we think about that. So, in general, the reason that the subgroup, I think, is important is because our patients, as they've aged and as we do more PCI in them, it's not always clear how they do with their bleeding and NACE [net adverse clinical events] events.

And so the study design is a subgroup of the PIONEER-AF trial, which I'll remind you was a phase 3 international trial that randomized patients with atrial fibrillation undergoing a PCI to 1 of 2 antithrombotic strategies: rivaroxaban, as you dose it for atrial fibrillation, or warfarin-based antithrombotic regimens. And the key endpoints in the study included net adverse clinical events, sometimes referred to as NACE, and that includes clinically significant bleeding and major adverse cardiovascular events. And the 2 dosing regimens of rivaroxaban in this trial, there's a lower dose and then the 15-mg dose, they were shown, again, in this study to be important, and they importantly reduced some of these events that I'll talk about in a second.

Now, the number of patients defined as elderly, which was defined as greater than or equal to 75 years of age, was about 34% in the study or 729 patients. And when they looked at the clinically significant bleeding rate at 12 months, a year after that PCI in this population getting the strategy, 21% had a bleeding event with the rivaroxaban dosing, and 31% had clinically significant bleeding with warfarin. So a significant 10% absolute risk reduction. And the number needed to treat around 10 or so. So this reduction in clinically significant bleeding was consistent across the elderly patients, but also the non-elderly, making sure that we saw the same benefit for the elderly that we saw in the younger patients. And again, that was for clinically significant bleeding. But when you then look at net adverse clinical events, which includes our patients that have the clinically significant bleeding, but then the major adverse cardiovascular events, again, there was a similar reduction with a hazard ratio of 0.77 in the non-elderly patients and the elderly patients, again, didn't have an interaction.

As you'll see on this KM curve, that these patients that had significant bleeding over 75 were much more often on warfarin compared to rivaroxaban. And I think this becomes important to our clinical practice because, as we start to see more and more patients aging with coronary disease and atrial fibrillation, we'll have more of these patients having a PCI and requiring some of these therapies.

So the abstract concludes, and I think it probably sits with your practice, that if you're taking care of patients with atrial fibrillation, that you should stay on the DOAC dose of rivaroxaban that you're using, even if you do a PCI, and then just modify, potentially, how you manage the length of that or if you're going to modify the antiplatelet therapy. But I would say, importantly, you should ensure that you stay away from warfarin in these patients because the DOACs certainly, in this study of rivaroxaban, seemed to have less bleeding and certainly have been observed not just to have less bleeding but similar NACE, if not less. So among both the elderly and the young in this study, there was a reduction in this net adverse cardiovascular event composition, which includes mostly clinically significant bleeding but then also, obviously, the major adverse cardiovascular events.

Thank you for listening. Hopefully you got an insight into the update from the American College of Cardiology. These are insights from the meeting recently for Duke Heart On The Go, and I appreciate you paying attention.

Announcer:

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