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Time needed to complete: 1h 18m

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VOYAGER-PAD Angiographic Core Lab: Design and Initial Results

Announcer:
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Dr. Rogers:
Hello, I'm Kevin Rogers. I'm going to speak about the VOYAGER-PAD Angiographic Core Lab: it's designed and initial results.

So peripheral artery disease is prevalent. It affects 230 million people worldwide, and 10% of these patients suffer adverse cardiovascular events. However, PAD patients are heterogeneous. For example, in the COMPASS trial, PAD patients with prior revascularization or amputation, had nearly threefold the event rates of major adverse limb events compared to patients with claudication but no history in the past of revascularization. However, sparse data exists regarding PAD anatomy and clinical outcomes.

Peripheral Artery Disease Anatomic Classification Systems do exist; however, Bollinger proposed perhaps the first in 1981, Graziani developed an Anatomic Scoring System for diabetics with critical limb ischemia. Schuyler Jones, Manesh Patel, and others developed an Anatomic Runoff Score in a dataset with cardiovascular outcomes. There's the more commonly referred to TASK classification and there's the more recent GLASS score for CLI. But these current anatomic scores are based on expert opinion or they're from datasets without associations with limb-specific outcomes.

The VOYAGER-PAD trial randomized 6,564 patients with symptomatic lower extremity peripheral artery disease undergoing peripheral revascularization. Eligibility for VOYAGER included having imaging evidence of occlusive peripheral artery disease. So a lot of effort was put forth to obtain angiograms from these patients who were included in VOYAGER with the purpose of creating a core lab. And as part of a randomized, trial independent adjudication of limb-specific events were available for analysis and correlation with anatomy.

This is the overall scheme of the VOYAGER-PAD angiographic core lab, anatomic and flow characteristics across 16 anatomic segments from 2,646 angiograms in the core lab database were collected. The objectives of the core lab were to look at these anatomic and flow characteristics and their association with longitudinal major adverse limb events, major adverse cardiovascular events, and patient-reported outcomes. We also plan to look at cross-sectional analyses and the relationships of these anatomic and flow characteristics with different PAD and clinical subgroups.

Our first stab at looking at the association of anatomy with major adverse outcomes was to generate a stenosis-length severity score, and look at its association with major adverse limit events in the index limb and participants in the core lab. The stenosis-length severity score is generated by assigning a stenosis severity score of 0 to 3 for different stenosis severity categories for each anatomic segment. And similarly, we assigned a length-severity score of 1 to 3 across different categories of length severity. For each segment, we then multiplied this stenosis severity score times the length-severity score, to generate a stenosis-length score product, which were then summed across all segments to generate a stenosis-length severity score for the entire limb. We divided the scores into tertile. And as

tertiles increased, patients tended to be older and were more likely to be black or have diabetes. Surprisingly, the prevalence of chronic kidney disease did not seem to change across tertiles. And smoking did not increase across tertiles as tertiles increased. At 3 years, those in the highest tertile of stenosis-length severity score had nearly twofold the major adverse limb event rates as compared to those in the middle tertile. And nearly sevenfold higher major adverse limb events as compared to the first tertile, and these differences were statistically significant. And finally, the stenosis-length severity score had a statistically significant area under the curve for discriminating which patients developed major adverse limb events compared to which patients who did not. And when added to the Rutherford score, the stenosis-length severity score has statistically significant increase in the area under the curve, and also had a significant increase when added to ABI and Rutherford alone.

So in conclusion, peripheral artery disease is prevalent and confers increased risk of limb events. Understanding how PAD anatomy contributes to risk may improve our understanding of risk stratification as it does in coronary artery disease. The VOYAGER-PAD angiographic core lab offers an important opportunity to better understand the relationships with anatomy outcomes in PAD subgroups. And finally, the stenosis-length severity score seems to add incremental predictive value for major adverse limb events to ABI and Rutherford category.

Thank you very much.

Announcer:
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