Risk Stratification for Amputation in Patients with Symptomatic Peripheral Artery Disease after Lower Extremity Revascularization: Insights from VOYAGER PAD

BACKGROUND

- Peripheral artery disease (PAD) is chronic arterial occlusive disease of lower extremities
- Chronic limb threatening ischemia (CLTI) is a severe manifestation characterized by ischemic rest pain and ischemic ulceration/dry gangrene
- Amputation is a severe consequence of peripheral artery disease (PAD)

METHODS

- The VOYAGER PAD trial randomized 6564 patients with PAD after LER to rivaroxaban 2.5 mg BID + ASA vs. placebo + ASA and followed for a median of 28 months
- Patients in the VOYAGER PAD trial were assigned a Rutherford Class by a trained investigator at baseline and follow up
- WIfI score was assigned based on protocol entry criteria; all foot infections were excluded based on trial protocol
- Incidence of the composite of first major or minor amputation through three years were calculated by risk group; RR of composite of major amp/ALI calculated by risk group

RESULTS

Incidence of Amputation at 3 years by Rutherford Classification

- Rutherford 1-2: 2.9% Major, 4.0% Minor
- Rutherford 3: 4.0% Major, 9.2% Minor
- Rutherford 4: 9.2% Major, 22.4% Minor

Incidence of Amputation at 3 years by WIfI in Patients With and Without Diabetes Mellitus

CONCLUSIONS

- In a recent large clinical trial of patients with symptomatic PAD post successful LER, high incidences of amputation were observed despite contemporary medical therapies suggesting systemic drivers of limb events
- Rutherford and WIfI both strata risk
- Those with WIfI "very low" risk still had high incidence of amputation
- Risk in those with diabetes was higher in each WIfI class suggesting that this clinical factor could be considered in risk stratification
- Rivaroxaban group had less risk of major amp/ALI at each Rutherford stage

REFERENCES

4. Mills et al. SVS Lower Extremity Threatened Limb Classification... JVS 2020;40(8):1808

DISCLOSURES

- VOYAGER was designed and overseen by a collaborative group that included Colorado Prevention Center (CPC) Clinical Research (an academic research organization affiliated with the University of Colorado), the academic executive committee and the sponsors, Bayer and Janssen Pharmaceuticals. JVS reports owning AstraZeneca stock and research funding from CPC Clinical Research. COF reports research funding from Merck, Bayer, and Amgen. ACS reports research funding from CPC Clinical Research. JF reports grants from AstraZeneca and research funding from CPC Clinical Research. JAD reports grants from Bayer and research funding from Merck and Company and AstraZeneca. SD reports research funding from CPC Clinical Research and grants from Boehringer Ingelheim and beyond. CNH reports research funding to CPC Clinical Research from Merck, Bayer, and Amgen. AS reports grants from AstraZeneca, research funding from Merck, and consulting fees from NovoNordisk. SD reports grant support and advisory board fees from Statin. SW reports consulting fees and lecture fees from Bristol Myers Squibb and Bayer. EM reports research funding from Merck, Bayer, and Amgen. LPH is employed by Janssen Pharmaceuticals and owns stock in Johnson & Johnson. RMB reports consulting fees and lecture fees from Bristol Myers Squibb. LPH is employed by Janssen Pharmaceuticals and owns stock in Johnson & Johnson. RMB reports consulting fees and lecture fees from Bristol Myers Squibb. LPH is employed by Janssen Pharmaceuticals and owns stock in Johnson & Johnson.

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