Applicability of the VOYAGER trial criteria: a cohort study on patients in the nationwide Danish Vascular Registry

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Introduction: Peripheral artery disease (PAD) carries a high risk of debilitating stroke, myocardial infarction, and death. The VOYAGER PAD trial investigates whether rivaroxaban 2.5 mg plus aspirin vs aspirin alone leads to a reduction in major adverse cardiovascular events (MACE) in patients with symptomatic PAD undergoing revascularization. However, it is unclear whether patients enrolled in VOYAGER PAD reflect those undergoing lower extremity revascularization in daily clinical practice.

Purpose: To describe the proportion of patients eligible for the VOYAGER PAD trial within the nationwide Danish Vascular Registry (DVR), the reasons for ineligible, and rates of cardiovascular outcomes in VOYAGER-eligible and VOYAGER-ineligible patients.

Methods: We identified and characterized all patients from 2000-2016 undergoing open surgical or endovascular revascularization for symptomatic PAD in the DVR and applied the VOYAGER inclusion and exclusion criteria. We computed one-year rates per 100 person-years of VOYAGER PAD trial endpoints of MACE, myocardial infarction, ischemic stroke, major amputation, major bleeding, cardiovascular (CV) death, and all cause death.

Results: In the DVR, 32,911 patients underwent lower extremity revascularization for symptomatic PAD and were evaluated for eligibility. Among these, 32.2% had at least one exclusion criteria and an additional 40.6% without exclusion criteria did not fulfill inclusion criteria. The ‘VOYAGER-eligible’ population therefore comprised 27.2% of the identified patients (Figure 1A). Main reasons for exclusion were atrial fibrillation (30.7%), poorly regulated hypertension (19.6%), PCI or ACS within 12 months before (16.0%), treatment with strong inhibitors or inducers of cytochrome P450 (9.2%), active cancer (8.8%), and severe renal failure (8.3%). Main reasons for non-inclusion were aorto-iliac procedures (79.0%), non-successful revascularization (13.1%), and age<50 years (7.1%). Compared with ‘VOYAGER-eligible’ patients, event rates were slightly lower among patients in the DVR not fulfilling inclusion criteria and markedly higher for ‘VOYAGER excluded’ patients (Figure 1B).

Conclusion: In this nationwide cohort of symptomatic PAD patients undergoing lower extremity revascularization, 27.2% full filled the inclusion and exclusion criteria for dual pathway therapy in the VOYAGER PAD trial. Non-inclusion predominantly related to aorto-iliac procedures and were associated with lower event rates. Future studies are needed to clarify if these patients could also benefit from dual pathway therapy.