Zeitschrift für
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Steiner S

Zeitschrift für Gefäßmedizin 2022;

19 (3), 15-16

Offizielles Organ der Österreichischen Gesellschaft für Phlebologie und dermatologische Angiologie

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ERWO PHARMA

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Rivaroxaban and risk of venous thromboembolism in patients with symptomatic peripheral artery disease after lower extremity revascularization

Hess CN, et al. JAMA Netw Open 2022; 5: e2215580.

Abstract

Importance: Prior studies have observed an association between the burden of atherosclerotic vascular disease and the risk of venous thromboembolism (VTE). The association is not well described in peripheral artery disease (PAD) after lower extremity revascularization (LER).
Objective: To describe the risk of, factors associated with, and outcomes after VTE, as well as the association of low-dose rivaroxaban plus antiplatelet therapy with VTE after LER.
Design, setting, and participants: This global, multicenter cohort study used data from the Vascular Outcomes Study of ASA (acetylsalicylic acid) Along With Rivaroxaban in Endovascular or Surgical Limb Revascularization for PAD (VOYAGER PAD) randomized clinical trial, which enrolled patients from 2015 to 2018 with median follow-up of 28 months. Participants included patients with PAD undergoing LER. Patients with an indication for therapeutic anticoagulation were excluded. Data were analyzed from September 2020 to September 2021.
Exposure: Randomization to rivaroxaban 2.5 mg twice daily or placebo on a background of aspirin 100 mg daily; short-term clopidogrel was used at the discretion of the treating physician.
Main outcomes and measures: Symptomatic VTE was a prespecified secondary outcome and prospectively collected.
Results: Among 6564 patients (median [IQR] age, 67 [61–73] years; 4860 [74.0%] men), 66 patients had at least 1 VTE. The 3-year rate of VTE in patients receiving placebo was 1.7%, and the pattern of risk was linear (year 1: 0.5%; year 2: 1.1%). After multivariable modeling, weight (hazard ratio [HR], 3.04; 95% CI, 1.09–8.43), hypertension (HR, 2.11; 95% CI, 0.91–4.89), prior amputation (HR, 2.07; 95% CI, 0.95–4.53), and older age (HR, 1.81; 95% CI, 1.06–3.11) were associated with increased risk of VTE. VTE was associated with risk of subsequent mortality (HR, 7.22; 95% CI, 4.66–11.19). Compared with aspirin alone, rivaroxaban plus aspirin was associated with lower VTE risk (HR, 0.61; 95% CI, 0.37–0.998; P = 0.047), with benefit apparent early and sustained over time. This association was not modified by use of clopidogrel at randomization (without clopidogrel: HR, 0.55; 95% CI, 0.29–1.07; with clopidogrel: HR, 0.69; 95% CI, 0.32–1.48; P for interaction = 0.67).
Conclusions and relevance: In this cohort study, there was continuous risk for VTE after LER in patients with PAD, with greater risk in patients who were older and had obesity and those with more severe PAD, as reflected by prior amputation. Low-dose rivaroxaban plus aspirin was associated with lower VTE risk compared with aspirin alone, with benefits apparent early and continued over time. The spectrum of venous and arterial thrombotic events and overall benefits of more potent antithrombotic strategies for prevention should be considered after LER for PAD.

Praxisrelevanz

Diese vordefinierte Analyse der Voyager-PAD-Studie zeigt auch einen klaren Nutzen der additiven, niedrigdosierten Rivaroxaban-Therapie in Hinblick auf die Reduktion venöser thromboembolischer Ereignisse.

Sex-based differences in periprocedural complications following lower extremity peripheral vascular intervention

Altin SE, et al. Circ Cardiovasc Interv 2022; 15: e011768.

Abstract

Background: Women with coronary artery disease are shown to have worse outcomes after percutaneous coronary intervention compared with men; however, less is known about sex-based outcomes following lower extremity peripheral vascular intervention (PVI) for symptomatic peripheral artery disease. The study aims to assess whether female sex is independently associated with periprocedural complications in patients undergoing PVI.
Methods: Analysis includes patients undergoing lower extremity PVI from September 2016 to March 2020 from the Vascular Quality Initiative registry. Multivariate logistic regression was used to assess the independent association of female sex with post-PVI complications.
Results: Of the 119 620 patients included, 47 316 (39.6%) were women. Analysis reflected that women were at higher risk of developing access site complications, including any hematoma (odds ratio [OR], 1.45 [1.35–1.57]), hematoma requiring transfusion (OR,

2.24 [1.82–2.76]; P < 0.001), hematoma requiring surgery (OR, 1.49 [1.19–1.86]; P < 0.001), pseudoaneurysm (OR, 1.69 [1.39–2.05]; P < 0.001), and access site occlusion (OR, 1.89 [1.15–3.08]; P < 0.001). Women also faced higher risks of target lesion dissection (OR, 1.36 [1.26–1.46]; P < 0.001), above-knee amputation (OR, 1.37 [1.18–1.58]; P < 0.001), and in-hospital mortality (OR, 1.21 [1.07–1.38]; P = 0.003).

Conclusions: In a contemporary cohort, women undergoing lower extremity PVI for symptomatic peripheral artery disease were at higher risk than men of developing periprocedural complications, including moderate or severe access site bleeding, above-knee amputation, and in-hospital mortality. This increased risk persisted despite adjustment for differences in baseline patient or procedural characteristics and warrants further investigation.

Praxisrelevanz

Trotz Adjustierung für Risikofaktoren zeigte sich in dieser großen Kohortenstudie ein deutlich erhöhtes Risiko für Patientinnen, verschiedene peri-interventionelle Komplikationen (z. B. Blutungen im Bereich der Punktionsstelle) zu erleiden, was bei der Betreuung dieser Patientinnen bedacht werden sollte.

Long-term efficacy and safety of moderate-intensity statin with ezetimibe combination therapy versus high-intensity statin monotherapy in patients with atherosclerotic cardiovascular disease (RACING): a randomised, open-label, non-inferiority trial

Kim BK, et al. Lancet 2022; 400: 380–90.

Abstract

Background: Drug combinations rather than increasing doses of one drug can achieve greater efficacy and lower risks. Thus, as an alternative to high-intensity statin monotherapy, moderate-intensity statin with ezetimibe combination therapy can lower LDL cholesterol concentrations effectively while reducing adverse effects. However, evidence from randomised trials to compare long-term clinical outcomes is needed.
Methods: In this randomised, open-label, non-inferiority trial, patients with atherosclerotic cardiovascular disease (ASCVD) at 26 clinical centres in South Korea were randomly assigned (1:1) to receive either moderate-intensity statin with ezetimibe combination therapy (rosuvastatin 10 mg with ezetimibe 10 mg) or high-intensity statin monotherapy (rosuvastatin 20 mg). The primary endpoint was the 3-year composite of cardiovascular death, major cardiovascular events, or non-fatal stroke, in the intention-to-treat population with a non-inferiority margin of 2.0%. This trial is registered with ClinicalTrials.gov, NCT03044665 and is complete.
Findings: Between Feb 14, 2017, and Dec 18, 2018, 3780 patients were enrolled: 1894 patients to the combination therapy group and 1886 to the high-intensity statin monotherapy group. The primary endpoint occurred in 172 patients (9.1%) in the combination therapy group and 186 patients (9.9%) in the high-intensity statin monotherapy group (absolute difference –0.78%; 90% CI –2.39 to 0.83). LDL cholesterol concentrations of less than 70 mg/dL at 1, 2, and 3 years were observed in 73%, 75%, and 72% of patients in the combination therapy group, and 55%, 60%, and 58% of patients in the high-intensity statin monotherapy group (all p < 0.0001). Discontinuation or dose reduction of the study drug by intolerance was observed in 88 patients (4.8%) and 150 patients (8.2%), respectively (p < 0.0001).
Interpretation: Among patients with ASCVD, moderate-intensity statin with ezetimibe combination therapy was non-inferior to high-intensity statin monotherapy for the 3-year composite outcomes with a higher proportion of patients with LDL cholesterol concentrations of less than 70 mg/dL and lower intolerance-related drug discontinuation or dose reduction.
Funding: Hanmi Pharmaceutical.

Praxisrelevanz

Die Studie unterstreicht die Wirksamkeit einer Kombinationstherapie aus Statin und Ezetimib und spielt so auch eine relevante Rolle für PAVK-Patienten, die häufig eine nicht ausreichende lipidsenkende Therapie erhalten.

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