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■ Ankle-Brachial index for risk stratification in patients with symptomatic peripheral artery disease with and without prior lower extremity revascularization: Observations from the EUCLID trial

Hiatt WR, et al. Circ Cardiovasc Interv 2021; 14: e009871.

Abstract

Background: A reduced ankle-brachial index (ABI) is a measure of atherosclerosis and is associated with ischemic risk in the general population. Whether this relationship is maintained in peripheral artery disease after lower extremity revascularization (LER), which can modify ABI, is unknown.

Methods: The EUCLID (Examining Use of Ticagrelor in Peripheral Artery Disease) enrolled 13 885 patients with symptomatic peripheral artery disease; 57% with prior LER, and 43% with ABI ≤ 0.80 . The primary major adverse cardiovascular events (MACE) outcome was a composite of cardiovascular death, myocardial infarction, or ischemic stroke. Major adverse limb events (MALE) included acute limb ischemia and major amputation. An adjusted Cox proportional hazards model demonstrated a nonlinear relationship

between ABI and outcomes. A restricted cubic spline model with 4 knots was developed to identify the best fitting model to describe the relationship between ABI and MACE and MALE risk.

Results: Baseline ABI (mean \pm SD) was 0.77 ± 0.21 in participants with prior LER and 0.63 ± 0.14 in those without prior LER ($P < 0.0001$). There was no statistical interaction between prior LER and ABI, meaning the shapes of the cubic spline models were similar between groups. In those with prior LER, for every 0.10 unit lower ABI below an ABI of 1.00, the hazard ratio for MACE was 1.08 (95% CI, 1.04–1.12; $P < 0.0001$), below an ABI of 0.80 the hazard ratio for MALE was 1.32 (95% CI, 1.21–1.43; $P < 0.0001$). In patients without prior LER, every 0.10 unit lower ABI below an ABI of 0.70 was associated with increased risk for MACE

(hazard ratio, 1.14 [95% CI, 1.06–1.23]; $P=0.0004$) and MALE (hazard ratio, 1.27 [95% CI, 1.08–1.49]; $P=0.003$).

Conclusions: Patients with established peripheral artery disease, particularly those with prior LER, have an increased risk of MACE and MALE. The ABI remains a strong predictor of MACE and MALE ischemic events with an inverse relationship below an ABI threshold for patients with and without prior LER.

■ Praxisrelevanz

Eine ABI-Messung nach vorangegangener Revaskularisation gibt nicht nur Auskunft über den Erfolg des Eingriffes, sondern ist auch ein Marker in Hinblick auf das weitere Risiko für schwere kardiovaskuläre Ereignisse und Extremitäten-Komplikationen.

Kommentar

In dieser Analyse aus Daten der EUCLID-Studie bestätigt sich die bekannte Wertigkeit der ABI-Messung als Prognosemarker für schwere kardiovaskuläre Ereignisse und Extremi-

täten-Komplikationen. Diese Beziehung besteht auch bei einer Messung nach erfolgter Revaskularisation der betroffenen Extremität.

■ Longitudinal assessment of safety of femoropopliteal endovascular treatment with paclitaxel-coated devices among medicare beneficiaries: The SAFE-PAD study

Secemsky EA, et al. JAMA Intern Med 2021; 181: 1071–80.

Abstract

Importance: Paclitaxel-coated peripheral devices have been associated with increased mortality, yet this harm signal has not been replicated outside of meta-analyses of small trials.

Objective: To provide a longitudinal assessment of the safety of femoropopliteal endovascular treatment with peripheral drug-coated devices (DCDs) among Medicare beneficiaries.

Design, setting, and participants: SAFE-PAD (Safety Assessment of

Femoropopliteal Endovascular Treatment With Paclitaxel-Coated Devices) was a retrospective cohort study designed with the US Food and Drug Administration to evaluate the noninferiority of mortality between DCDs and non-drug-coated devices (NDCDs) for femoropopliteal revascularization performed in 2978 inpatient and outpatient facilities in the US from April 1, 2015, through December 31, 2018. Evaluation of the primary outcome was assessed

through May 31, 2020. Participants were Medicare fee-for-service beneficiaries 66 years and older with 1 or more years of enrollment prior to femoropopliteal revascularization. Prespecified subgroups included low-risk cohorts, procedure location, disease severity, and device type. Inverse probability weighting was used to account for imbalances of observed characteristics. Sensitivity analyses were used to evaluate the potential influence of unmeasured confounding.

Exposures: Treatment with DCDs vs NDCDs as determined by claims codes during the index procedure.

Main outcomes and measures: The primary outcome was all-cause mortality. Secondary outcomes included repeated hospitalization, repeated lower extremity revascularization, and lower extremity amputation. Falsification end points were acute myocardial infarction, congestive heart failure, and pneumonia.

Results: Of 168 553 patients, 70 584 (41.9%) were treated with a DCD. The mean (SD) age was 77.0 (7.6) years, 75 744 (44.9%) were female, 136 916 of 167 197 (81.9%) were White individuals, 85 880 of 168 553 (51.0%) had diabetes, 82 554 of 168 553 (49.0%) used tobacco, 78 665 of 168 553 (45.7%) had critical limb ischemia (CLI), and 13 296 of 168 553 (7.9%) had a prior amputation. Median follow-up was 2.72 years (interquartile range, 0.87–3.77;

longest, 5.16 years). After weighting, the cumulative incidence of all-cause mortality was 53.8% with DCDs and 55.1% with NDCDs (hazard ratio [HR], 0.95; 95% CI, 0.94–0.97; noninferiority $P < 0.001$). Cox regression and instrumental variable analyses were consistent with the primary findings. No harm associated with DCDs was observed among subgroups, including those treated with stents (HR, 0.97; 95% CI, 0.95–1.00) or balloons (HR, 0.94; 95% CI, 0.92–0.96), with or without CLI (CLI: HR, 0.95; 95% CI, 0.93–0.97; non-CLI: HR, 0.97; 95% CI, 0.95–0.99), and those within the lowest quartile of total comorbidities (HR, 0.95; 95% CI, 0.92–0.99).

Conclusions and Relevance: In this initial report from the SAFE-PAD cohort study, DCDs were found to be noninferior to NDCDs in respect to mortality through a median follow-up of 2.72

years. This finding remained robust in sensitivity analyses and was consistent across prespecified subgroups.

Praxisrelevanz

In den für diese Studie verwendeten Medicare-Kohortendaten mit über 168.000 eingeschlossenen Patienten zeigte sich kein Hinweis einer erhöhten Langzeit-Mortalität nach Verwendung von Paclitaxel freisetzenden Ballonen oder Stents im Vergleich zu unbeschichteten Devices bei femoropoplitealen endovaskulären Eingriffen. Aufgrund der zahlreichen Analysen aus verschiedensten Datenquellen, die die Sicherheit von Paclitaxel bei femoropoplitealen Interventionen unterstreichen, fordern immer mehr Experten, dass entsprechende Warnungen der Gesundheitsbehörden modifiziert werden.

■ Prognostic value of radiotracer-based perfusion imaging in critical limb ischemia patients undergoing lower extremity revascularization

Chou TH, et al. JACC Cardiovasc Imaging 2021; 14: 1614–24.

Abstract

Objectives: The purpose of this study was to evaluate the prognostic value of single-photon emission computed tomography (SPECT)/computed tomography (CT) imaging of angiosome foot perfusion for predicting amputation outcomes in patients with critical limb ischemia (CLI) and diabetes mellitus (DM).

Background: Radiotracer imaging can assess microvascular foot perfusion and identify regional perfusion abnormalities in patients with critical limb ischemia CLI and DM, but the relationship between perfusion response to revascularization and subsequent clinical outcomes has not been evaluated.

Methods: Patients with CLI, DM, and nonhealing foot ulcers ($n = 25$) were prospectively enrolled for SPECT/CT perfusion imaging of the feet before and after revascularization. CT images were used to segment angiosomes (i.e., 3-dimensional vascular territories) of

the foot. Relative changes in radiotracer uptake after revascularization were evaluated within the ulcerated angiosome. Incidence of amputation was assessed at 3 and 12 months after revascularization.

Results: SPECT/CT detected a significantly lower microvascular perfusion response for patients who underwent amputation compared with those who remained amputation free at 3 ($p = 0.01$) and 12 ($p = 0.01$) months after revascularization. The cutoff percent change in perfusion for predicting amputation at 3 months was 7.55%, and 11.56% at 12 months. The area under the curve based on the amputation outcome was 0.799 at 3 months and 0.833 at 12 months. The probability of amputation-free survival was significantly higher at 3 ($p = 0.002$) and 12 months ($p = 0.03$) for high-perfusion responders than low-perfusion responders to revascularization.

Conclusions: SPECT/CT imaging detects regional perfusion responses to lower extremity revascularization and provides prognostic value in patients with CLI. (Radiotracer-Based Perfusion Imaging of Patients With Peripheral Arterial Disease; NCT03622359)

Praxisrelevanz

Zur Diagnosestellung der chronisch-kritischen Extremitätenischämie stehen verschiedene Methoden zur Verfügung, jedoch ist ihre Rolle zur Vorhersage des Amputationsrisikos weniger etabliert. Die hier vorgestellte Perfusionsmessung mittels SPECT/CT könnte eine interessante Option darstellen, wobei dies aufgrund der eingeschränkten Verfügbarkeit wahrscheinlich nur in ausgewählten Patienten oder im Rahmen klinischer Studien möglich ist.

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