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SYMPOSIUM

Ein neuer Angriffspunkt im leitliniengerechten Risikofaktorenmanagement von pAVK- Patient:innen

Dr. Reinhard B. Raggam, Graz

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AT-VAZ-00220, 05/2025

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Long-term outcomes following endovascular and surgical revascularization for peripheral artery disease: a propensity score-matched analysis

Parvar SL, et al. Eur Hear J 2022; 43: 32–40.

Abstract

Aims: Peripheral artery disease (PAD) revascularization can be performed by either endovascular or open surgical approach. Despite increasing use of endovascular revascularization, it is still uncertain which strategy yields better long-term outcomes.
Methods and Results: This retrospective cohort study evaluated patients hospitalized with PAD in Australia and New Zealand who underwent either endovascular or surgical revascularization between 2008 and 2015, and compared procedures using a propensity score-matched analysis. Hybrid interventions were excluded. The primary endpoint was mortality or major adverse limb events (MALE), defined as a composite endpoint of acute limb ischaemia, urgent surgical or endovascular reintervention, or major amputation, up to 8 years post-hospitalization using time-to-event analyses 75 189 patients fulfilled eligibility (15,239 surgery and 59,950 endovascular), from whom 14,339 matched pairs (mean ± SD age 71 ± 12 years, 73% male) with good covariate balance were identified. Endovascular revascularization was associated with an increase in combined MALE or mortality (hazard ratio [HR] 1.13, 95% confidence interval [CI]: 1.09–1.17, P < 0.001). There was a similar risk of MALE (HR 1.04, 95% CI: 0.99–1.10, P = 0.15), and all-cause urgent rehospitalizations (HR 1.01, 95% CI: 0.98–1.04, P = 0.57), but higher mortality (HR 1.16, 95% CI: 1.11–1.21, P < 0.001) when endovascular repair was compared to surgery. In subgroup analysis, these findings were consistent for both claudication and chronic limb-threatening ischaemia presentations.
Conclusion: Although the long-term risk of MALE was comparable for both approaches, enduring advantages of surgical revascularization included lower long-term mortality. This is at odds with some prior PAD studies and highlights contention in this space.

Kommentar

Endovaskuläre Eingriffe im Bereich der A. femoralis superficialis und proximalen A. poplitea sind die häufigsten peripheren Interventionen. In den ESC-Leitlinien 2017 zur Diagnose und Behandlung von peripheren Arterienerkrankungen wird empfohlen, bei femoropoplitealen Läsionen < 25 cm zunächst eine endovaskuläre Therapie in Betracht zu ziehen. Direkte Vergleichsstudien zwischen operativer und endovaskulärer Revaskularisierung bei langen, komplexen Läsionen über 25 cm sind nur sehr eingeschränkt verfügbar, wobei in nächster Zeit Ergebnisse von großen laufenden Studien zu erwarten sind.

Rezente größere Beobachtungsstudien nützen meistens einen mittels Propensity-Score-Matching adjustierten Vergleich. Frühere Studien berichteten hier wiederholt einen Mortalitätsvorteil für ein endovaskuläres Vorgehen, was im Gegensatz zu dieser retrospektiven Kohortenstudie aus Australien und Neuseeland steht.

Praxisrelevanz

Direkte Vergleichsstudien für femoropopliteale, aber auch infrapopliteale Revaskularisation mittels Bypass versus endovaskulärer Technik sind nur eingeschränkt, mit wesentlichen Limitationen, verfügbar. Kohortenstudien, deren Analysen auf Propensity-Score-Matching basieren, zeigen unterschiedliche Ergebnisse, auch in Hinblick auf das Mortalitätsrisiko.
In der klinischen Routine ist sicher eine gemeinsame Entscheidungsfindung des Gefäßteams mit dem Patienten eine optimale Lösung. Insbesondere sollte darauf geachtet werden, dass für einen eventuell notwendigen Folgeeingriff mittels der jeweils anderen Technik weiterhin möglichst gute Bedingungen erhalten werden.

Fixed-dose combination therapies with and without aspirin for primary prevention of cardiovascular disease: an individual participant data meta-analysis

Joseph P, et al. Lancet 2021; 398: 1133–46.

Abstract

Background: In randomised controlled trials, fixed-dose combination treatments (or polypills) have been shown to reduce a composite of cardiovascular disease outcomes in primary prevention. However, whether or not aspirin should be included, effects on specific outcomes, and effects in key subgroups are unknown.
Methods: We did an individual participant data meta-analysis of large randomised controlled trials (each with ≥ 1000 participants and ≥ 2 years of follow-up) of a fixed-dose combination treatment strategy versus control in a primary cardiovascular disease prevention population. We included trials that evaluated a fixed-dose combination

strategy of at least two blood pressure lowering agents plus a statin (with or without aspirin), compared with a control strategy (either placebo or usual care). The primary outcome was time to first occurrence of a composite of cardiovascular death, myocardial infarction, stroke, or arterial revascularisation. Additional outcomes included individual cardiovascular outcomes and death from any cause. Outcomes were also evaluated in groups stratified by the inclusion of aspirin in the fixed-dose treatment strategy, and effect sizes were estimated in prespecified subgroups based on risk factors. Kaplan-Meier survival curves and Cox proportional hazard regression models were used to compare strategies.
Findings: Three large randomised trials were included in the analysis (TIPS-3, HOPE-3, and PolyIran), with a total of 18,162 participants. Mean age was 63.0 years (SD 7. 1), and 9038 (49.8%) participants were female. Estimated 10-year cardiovascular disease risk for the population was 17. 7% (8.7). During a median follow-up of 5 years, the primary outcome occurred in 276 (3·0%) participants in the fixed-dose combination strategy group compared with 445 (4·9%) in the control group (hazard ratio 0·62, 95% CI 0·53-0·73, p<0·0001). Reductions were also observed for the separate components of the primary outcome: myocardial infarction (0.52, 0.38–0.70), revascularisation (0.54, 0.36–0.80), stroke (0.59, 0.45–0.78), and cardiovascular death (0.65, 0.52–0.81). Significant reductions in the primary outcome and its components were observed in the analyses of fixed-dose combination strategies with and without aspirin, with greater reductions for strategies including aspirin. Treatment effects were similar at different lipid and blood pressure levels, and in the presence or absence of diabetes, smoking, or obesity. Gastrointestinal bleeding was uncommon but slightly more frequent in the fixed-dose combination strategy with aspirin group versus control (19 [0.4%] vs 11 [0.2%], p = 0·15). The frequencies of haemorrhagic stroke (10 [0.2%] vs 15 [0.3%]), fatal bleeding (two [< 0.1%] vs four [0.1%]), and peptic ulcer disease (32 [0.7%] vs 34 [0.8%]) were low and did not differ significantly between groups. Dizziness was more common with fixed-dose combination treatment (1060 [11.7%] vs 834 [9.2%], p < 0.0001).
Interpretation: Fixed-dose combination treatment strategies substantially reduce cardiovascular disease, myocardial infarction, stroke, revascularisation, and cardiovascular death in primary cardiovascular disease prevention. These benefits are consistent irrespective of cardiometabolic risk factors.

Praxisrelevanz

Das Konzept der Polypill, bestehend aus zwei Antihypertensiva und einem Statin, zeigt eindeutig einen Benefit in der Primärprophylaxe kardiovaskulärer Erkrankungen mit einer konsistenten Reduktion von fatalen und nichtfatalen kardiovaskulären Ereignissen. Ein Hinweis über einen zusätzlichen Nutzen einer Aspirin-Therapie in dieser Indikation ist jedoch deutlich weniger klar und widerspricht hier auch anderen randomisierten Studien.

Effect of evolocumab on acute arterial events across all vascular territories : results from the FOURIER trial

Oyama K, et al. Eur Heart J 2021; 42: 4821–9.

Abstract

Aims: We assessed the impact of the proprotein convertase subtilisin-kexin type 9 (PCSK9) inhibitor evolocumab on acute arterial events across all vascular territories, including coronary, cerebrovascular, and peripheral vascular beds, in patients with established atherosclerotic cardiovascular disease (ASCVD).
Methods and Results: In the FOURIER trial, 27,564 patients with stable ASCVD on statin therapy were randomly assigned to evolocumab or placebo. Acute arterial events were a composite of acute coronary (coronary heart disease death, myocardial infarction, or urgent coronary revascularization), cerebrovascular (ischaemic stroke, transient ischaemic attack, or urgent cerebral revascularization), or peripheral vascular (acute limb ischaemia, major amputation, or urgent peripheral revascularization) events. Of the 2210 first acute arterial events, 74% were coronary, 22% were cerebrovascular, and 4% were peripheral vascular. Evolocumab reduced first acute arterial events by 19% (hazard ratio [HR] 0.81 [95% confidence interval 0.74–0.88]; P < 0.001), with significant individual reductions in acute coronary (HR 0.83 [0.75-0.91]), cerebrovascular (HR 0.77 [0.65-0.92]), and peripheral vascular (HR 0.58 [0.38–0.88]) events. There were 3437 total events (first plus recurrent), with evolocumab reducing total events by 24% (incidence rate ratio 0.76 [0.69–0.85]). The magnitude of reduction in acute arterial events with evolocumab numerically increased over time, with a 16% reduction (HR 0.84 [0.75–0.95]) in the first year followed by a 24% reduction (HR 0.76 [0.67–0.85]) thereafter.
Conclusion: The addition of the PCSK9 inhibitor evolocumab to statin therapy reduced acute arterial events across all vascular territories with a robust effect over time, indicating a pan-vascular impact of aggressive lipid-lowering therapy on these acute and clinically meaningful events.
Clinical trial registration:
URL: https://www.clinicaltrials.gov. Unique identifier: NCT01764633.

Praxisrelevanz

In einer Subgruppen-Analyse der FOURIER-Studie bei PAVK-Patienten zeigte der PCSK-9-Inhibitor Evolocumab bereits einen hohen Nutzen in Hinblick auf die Verhinderung kardiovaskulärer Ereignisse in diesem Hochrisiko-Patientenkollektiv. In dieser rezenten Analyse konnte nun belegt werden, dass durch eine intensive Lipidsenkung akute Ereignisse in allen Gefäßgebieten signifikant reduziert werden können. Zwar waren periphere Gefäßereignisse numerisch deutlich seltener als koronare oder zerebrovaskuläre Ereignisse, aber die relative Risikoreduktion durch Evolocumab war hier besonders deutlich.

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