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## News-Screen

Steiner S

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# News-Screen

S. Steiner

Aus der Klinik und Poliklinik für Angiologie, Universität Leipzig

## ■ Association of Factor V Leiden with subsequent atherothrombotic events: A GENIUS-CHD study of individual participant data

*Mahmoodi BK et al. Circulation 2020 Jul 13. Online ahead of print.*

### Abstract

**Background:** Studies examining the role of factor V Leiden among patients at higher risk of atherothrombotic events, such as those with established coronary heart disease (CHD) are lacking. Given that coagulation is involved in the thrombus formation stage upon atherosclerotic plaque rupture, we hypothesized that factor V Leiden may be a stronger risk factor for atherothrombotic events in patients with established CHD.

**Methods:** We performed an individual-level meta-analysis including 25 prospective studies (18 cohorts, 3 case-cohorts, 4 randomized trials) from the GENIUS-CHD consortium involving patients with established CHD at baseline. Participating studies genotyped factor V Leiden status and shared risk estimates for the outcomes of interest using a centrally developed statistical code with harmonized definitions across studies. Cox-regression models were used to obtain age and sex adjusted estimates. The obtained estimates

were pooled using fixed-effect meta-analysis. The primary outcome was composite of myocardial infarction and CHD death. Secondary outcomes included any stroke, ischemic stroke, coronary revascularization, cardiovascular mortality and all-cause mortality.

**Results:** The studies included 69,681 individuals of whom 3,190 (4.6%) were either heterozygous or homozygous ( $n = 47$ ) carriers of factor V Leiden. Median follow-up per study ranged from 1.0 to 10.6 years. A total of 20 studies with 61,147 participants and 6,849 events contributed to analyses of the primary outcome. Factor V Leiden was not associated with the combined outcome of myocardial infarction and CHD death (hazard ratio, 1.03; 95% CI, 0.92–1.16;  $I^2 = 28\%$ ; P-heterogeneity = 0.12). Subgroup analysis according to baseline characteristics or strata of traditional cardiovascular risk factors did not show relevant differences. Similarly, risk estimates for the secondary outcomes including

stroke, coronary revascularization, cardiovascular mortality and all-cause mortality were close to identity.

**Conclusions:** Factor V Leiden was not associated with increased risk of subsequent atherothrombotic events and mortality in high-risk participants with established and treated CHD. Routine assessment of factor V Leiden status is unlikely to improve atherothrombotic events risk stratification in this population.

### Praxisrelevanz

Eine potenzielle Rolle von etablierten Risikofaktoren für venöse Thromboembolien auch bei der Entstehung atherothrombotischer Ereignisse wird immer wieder diskutiert. In dieser großangelegten Studie aufbauend auf individuellen Patientendaten konnte kein Einfluss der Faktor-V-Leiden-Mutation in Hinblick auf kardiovaskuläre Ereignisse und Mortalität gezeigt werden.

## ■ Association of statin use with all-cause and cardiovascular mortality in US veterans 75 years and older

*Orkaby AR, et al. JAMA 2020; 324: 68–78.*

### Abstract

**Importance:** Data are limited regarding statin therapy for primary prevention of atherosclerotic cardiovascular disease (ASCVD) in adults 75 years and older.

**Objective:** To evaluate the role of statin use for mortality and primary prevention of ASCVD in veterans 75 years and older.

**Design, setting, and participants:** Retrospective cohort study that used Veterans Health Administration (VHA) data on adults 75 years and older, free of ASCVD, and with a clinical visit in 2002–2012. Follow-up continued

through December 31, 2016. All data were linked to Medicare and Medicaid claims and pharmaceutical data. A new-user design was used, excluding those with any prior statin use. Cox proportional hazards models were fit to evaluate the association of statin use with outcomes. Analyses were conducted using propensity score overlap weighting to balance baseline characteristics.

**Exposures:** Any new statin prescription.  
**Main outcomes and measures:** The primary outcomes were all-cause and cardiovascular mortality. Secondary

outcomes included a composite of ASCVD events (myocardial infarction, ischemic stroke, and revascularization with coronary artery bypass graft surgery or percutaneous coronary intervention).

**Results:** Of 326 981 eligible veterans (mean [SD] age, 81.1 [4.1] years; 97% men; 91% white), 57 178 (17.5%) newly initiated statins during the study period. During a mean follow-up of 6.8 (SD, 3.9) years, a total 206 902 deaths occurred including 53 296 cardiovascular deaths, with 78.7 and 98.2 total deaths/1000 person-years among statin

users and nonusers, respectively (weighted incidence rate difference [IRD]/1000 person-years, -19.5 [95% CI, -20.4 to -18.5]). There were 22.6 and 25.7 cardiovascular deaths per 1000 person-years among statin users and nonusers, respectively (weighted IRD/1000 person-years, -3.1 [95% CI, -3.6 to -2.6]). For the composite ASCVD outcome there were 123 379 events, with 66.3 and 70.4 events/1000 person-years among statin users and nonusers, respectively (weighted IRD/1000 person-years, -4.1 [95% CI, -5.1 to -3.0]). After propensity score overlap weighting was applied, the hazard ratio was 0.75 (95% CI, 0.74–0.76) for all-cause mortality, 0.80 (95% CI, 0.78–0.81) for cardiovascular mortality, and 0.92 (95% CI, 0.91–0.94) for a composite of ASCVD events when comparing statin users with nonusers.

**Conclusions and relevance:** Among US veterans 75 years and older and free of ASCVD at baseline, new statin use was significantly associated with a lower risk of all-cause and cardiovascular mortality. Further research, including from randomized clinical trials, is needed to more definitively determine the role of statin therapy in older adults for primary prevention of ASCVD.

### Praxisrelevanz

Aufgrund der eingeschränkten Datenlage aus randomisierten Studien ist die Rolle von Statinen zur kardiovaskulären Primärprävention insbesondere bei älteren Personen unklar. In dieser retrospektiven Kohortenstudie zeigt sich bei > 75-jährigen Teilnehmern ohne bekannte kardiovaskuläre Vorerkrankung ein klarer Vorteil in Hinblick auf kardiovaskuläre und Gesamt-Mortalität durch eine neu verordnete Statintherapie. Diese Ergebnisse sprechen für eine Statineinnahme auch bei älteren Patienten zur Primärprävention.

## ■ Midterm outcomes of percutaneous deep venous arterialization with a dedicated system for patients with no-option chronic limb-threatening ischemia: The ALPS multicenter study

Schmidt A, et al. *J Endovasc Ther* 2020 [E-pub ahead of print].

### Abstract

**Purpose:** To evaluate the midterm results of patients suffering from no-option chronic limb-threatening ischemia (CLTI) treated with a dedicated system for percutaneous deep venous arterialization (pDVA).

**Materials and Methods:** Thirty-two consecutive CLTI patients (mean age  $67 \pm 14$  years; 20 men) treated with pDVA using the Limflow device at 4 centers between 11 July 2014 and 11 June 2018 were retrospectively analyzed. Of all patients, 21 (66%) had diabetes, 8 (25%) were on immunosuppression, 4 (16%) had dialysis-dependent renal failure, 9 (28%) had Rutherford category 6 ischemia, and 25 (78%) were deemed at high risk of amputation. The primary outcome was amputation-free survival (AFS) at 6 months. Secondary outcomes were wound healing, limb salvage, and survival at 6, 12, and 24 months.

**Results:** Technical success was achieved in 31 patients (96.9%). The median follow-up was 34 months (range 16–63). At 6, 12, and 24 months, estimates were 83.9%, 71.0%, and 67.2% for AFS, 86.8%, 79.8% and 79.8% for limb salvage, and 36.6%, 68.2%, and 72.7% for complete wound healing, respectively. Median time to complete wound healing was 4.9 months (range 0.5–15).

The DVA circuit occluded during follow-up in 21 patients; the median time to occlusion was 2.6 months. Reintervention for occlusion was performed in 17 patients: 16 because of unhealed wounds and 1 for a newly developed ulcer.

**Conclusion:** This study represents the largest population of patients with no-option CLTI treated with pDVA using the LimFlow device with midterm results. In this complex group of patients, pDVA using the LimFlow device

has been shown to be feasible, with a high technical success rate and AFS at 6 up to 24 months coupled with wound healing. In selected patients with no-option CLTI, pDVA could be a recommended treatment to prevent amputation and heal wounds.

### Praxisrelevanz

Das Konzept der endovaskulären Arterialisierung tiefer Venen hat sich in den vergangenen Jahren als letzte Revaskularisationsoption bei kritischer Extremitätenischämie entwickelt. Diese bislang größte publizierte Serie zeigt ein positives 1-Jahres amputationsfreies Überleben von ca. 70 % bei 32 behandelten Patienten. Für ausgewählte Patienten kann diese Option in spezialisierten Zentren überlegt werden.

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