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News-Screen

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Antiplatelet Therapy vs Anticoagulation Therapy in Cervical Artery Dissection: The Cervical Artery Dissection in Stroke Study (CADISS) Randomized Clinical Trial Final Results

Markus HS et al. JAMA Neurol 2019 Feb 25. doi: 10.1001/jamaneurol.2019.0072. [Epub ahead of print]

Abstract

Importance: Extracranial carotid and vertebral artery dissection is an important cause of stroke, particularly in younger individuals. In some but not all observational studies, it has been associated with a high risk of recurrent stroke. Both antiplatelet agents (APs) and anticoagulants (ACs) are used to reduce stroke risk, but whether 1 treatment strategy is more effective is unknown.

Objective: To determine whether AP or AC therapy is more effective in preventing stroke in cervical dissection and the risk of recurrent stroke in a randomized clinical trial setting. A secondary outcome was to determine the effect on arterial imaging outcomes.

Design, Setting and Participants: Randomized, prospective, open-label international multicenter parallel design study with central blinded review of both clinical and imaging end points. Recruitment was conducted in 39 stroke and neurology secondary care centers in the United Kingdom and 7

centers in Australia between February 24, 2006, and June 17, 2013. One-year follow-up and analysis was conducted in 2018. Two hundred fifty participants with extracranial carotid and vertebral dissection with symptom onset within the last 7 days were recruited. Follow-up data at 1 year were available for all participants.

Interventions: Randomization to AP or AC (heparin followed by warfarin) for 3 months, after which the choice of AP and AC agents was decided by the local clinician.

Main Outcomes and Measures: The primary end point was ipsilateral stroke and death. A planned per protocol (PP) analysis was performed in patients meeting the inclusion criteria following central review of imaging to confirm the diagnosis of dissection. A secondary end point was angiographic recanalization in those with imaging confirmed dissection.

Results: Two hundred fifty patients were randomized (118 carotid and 132

vertebral), 126 to AP and 124 to AC. Mean (SD) age was 49 (12) years. Mean (SD) time to randomization was 3.65 (1.91) days. The recurrent stroke rate at 1 year was 6 of 250 (2.4%) on ITT analysis and 5 of 197 (2.5%) on PP analysis. There were no significant differences between treatment groups for any outcome. Of the 181 patients with confirmed dissection and complete imaging at baseline and 3 months, there was no difference in the presence of residual narrowing or occlusion between those receiving AP ($n=56$ of 92) vs those receiving AC ($n=53$ of 89) ($P=0.97$).

Conclusions and Relevance: During 12 months of follow-up, the number of recurrent strokes was low. There was no difference between treatment groups in outcome events or the rate of recanalization.

Trial Registration: ISRCTN.com Identifier: CTN44555237.

Kommentar

In der CADISS-Studie wurde untersucht, ob durch eine Thrombozytenfunktionshemmung oder durch eine Gerinnungshemmung (Heparin gefolgt von Vitamin-K-Antagonisten) eine bessere Schlaganfallprophylaxe bei Patienten nach Dissektion der extrakraniellen A. vertebralis oder A. carotis erzielt werden kann. Insgesamt zeigte sich kein Unterschied in Hinblick auf das Auftreten von Schlaganfällen nach einer Nachbeobachtung von 12 Monaten bei einer insgesamt sehr niedrigen Ereignisrate. Auffällig war, dass ein Insult im Follow-up nur bei Patienten

auftrat, die auch im Rahmen des Initialereignisses ein solches Ereignis hatten.

Praxisrelevanz

Bei Karotis- oder Vertebraldissektion konnte keine Überlegenheit von Vitamin-K-Antagonisten versus Thrombozytenaggregationshemmern gezeigt werden. Die Wertigkeit von neuen oralen Antikoagulantien bleibt unklar, da entsprechende Untersuchungen weiterhin fehlen.

Efficacy and safety of statin therapy in older people: a meta-analysis of individual participant data from 28 randomised controlled trials

Cholesterol Treatment Trialists' Collaboration. Lancet 2019; 393: 407–15.

Abstract

Background: Statin therapy has been shown to reduce major vascular events and vascular mortality in a wide range of individuals, but there is uncertainty about its efficacy and safety among older people. We undertook a meta-analysis of data from all large statin trials to compare the effects of statin therapy at different ages.

Methods: In this meta-analysis, randomised trials of statin therapy were eligible if they aimed to recruit at least 1000 participants with a scheduled treatment duration of at least 2 years. We analysed individual participant data from 22 trials ($n = 134,537$) and detailed summary data from one trial ($n = 12,705$) of statin therapy versus control, plus individual participant data from five trials of more intensive versus less intensive statin therapy ($n = 39,612$). We subdivided participants into six age groups (55 years or younger, 56–60 years, 61–65 years, 66–70 years, 71–75 years, and older than 75 years). We estimated effects on major vascular events (ie, major coronary events, strokes, and coronary revascularisations), cause-specific mortality, and cancer incidence as the rate ratio (RR) per 1.0 mmol/L reduction in LDL cholesterol. We compared proportional risk reductions in different age subgroups by use of standard χ^2 tests for heterogeneity when there were two groups, or trend when there were more than two groups.

Findings: 14,483 (8%) of 186,854 participants in the 28 trials were older than

75 years at randomisation, and the median follow-up duration was 4.9 years. Overall, statin therapy or a more intensive statin regimen produced a 21% (RR 0.79, 95% CI 0.77–0.81) proportional reduction in major vascular events per 1.0 mmol/L reduction in LDL cholesterol. We observed a significant reduction in major vascular events in all age groups. Although proportional reductions in major vascular events diminished slightly with age, this trend was not statistically significant (p -trend = 0.06). Overall, statin or more intensive therapy yielded a 24% (RR 0.76, 95% CI 0.73–0.79) proportional reduction in major coronary events per 1.0 mmol/L reduction in LDL cholesterol, and with increasing age, we observed a trend towards smaller proportional risk reductions in major coronary events (p -trend = 0.009). We observed a 25% (RR 0.75, 95% CI 0.73–0.78) proportional reduction in the risk of coronary revascularisation procedures with statin therapy or a more intensive statin regimen per 1.0 mmol/L lower LDL cholesterol, which did not differ significantly across age groups (p -trend = 0.6). Similarly, the proportional reductions in stroke of any type (RR 0.84, 95% CI 0.80–0.89) did not differ significantly across age groups (p -trend = 0.7). After exclusion of four trials which enrolled only patients with heart failure or undergoing renal dialysis (among whom statin therapy has not been shown to be effective), the trend to smaller proportional

risk reductions with increasing age persisted for major coronary events (p -trend = 0.01), and remained non-significant for major vascular events (p -trend = 0.3). The proportional reduction in major vascular events was similar, irrespective of age, among patients with pre-existing vascular disease (p -trend = 0.2), but appeared smaller among older than among younger individuals not known to have vascular disease (p -trend = 0.05). We found a 12% (RR 0.88, 95% CI 0.85–0.91) proportional reduction in vascular mortality per 1.0 mmol/L reduction in LDL cholesterol, with a trend towards smaller proportional reductions with older age (p -trend = 0.004), but this trend did not persist after exclusion of the heart failure or dialysis trials (p -trend = 0.2). Statin therapy had no effect at any age on non-vascular mortality, cancer death, or cancer incidence.

Interpretation: Statin therapy produces significant reductions in major vascular events irrespective of age, but there is less direct evidence of benefit among patients older than 75 years who do not already have evidence of occlusive vascular disease. This limitation is now being addressed by further trials.

Funding: Australian National Health and Medical Research Council, National Institute for Health Research Oxford Biomedical Research Centre, UK Medical Research Council, and British Heart Foundation.

Praxisrelevanz

Der Nutzen von Statinen zur Reduktion kardiovaskulärer Ereignisse ist klar belegt, wobei jedoch in den einzelnen Studien die meisten Teilnehmer < 75 Jahre alt waren. In dieser Meta-Analyse basierend auf individuellen Patientendaten konnten Vorteile einer

Statintherapie in der Sekundärprävention auch bei >75-Jährigen belegt werden. In der Primärprävention war der Effekt jedoch deutlich geringer und die Wertigkeit einer Statintherapie bei älteren Personen mit dieser Indikation ist daher weiterhin unklar.

■ Control of blood pressure and risk of mortality in a cohort of older adults: the Berlin Initiative Study

Douros A et al. Eur Heart J 2019 Feb 25 [Epub ahead of print].

Abstract

Aims: To assess whether blood pressure (BP) values below 140/90 mmHg during antihypertensive treatment are associated with a decreased risk of all-cause mortality in community-dwelling older adults.

Methods and Results: Within the Berlin Initiative Study, we assembled a cohort of patients ≥ 70 years treated with antihypertensive drugs at baseline (November 2009–June 2011). End of prospective follow-up was December 2016. Cox proportional hazards models yielded adjusted hazard ratios (HRs) and 95% confidence intervals (CIs) of all-cause mortality associated with normalized BP [systolic BP (SBP) < 140 mmHg and diastolic BP (DBP) < 90 mmHg] compared with non-normalized BP (SBP ≥ 140 mmHg or DBP ≥ 90 mmHg) overall and after stratification by age or previous cardiovascular events. Among 1628 patients (mean age 81 years) on antihypertensive drugs, 636 exhibited

normalized BP. During 8853 person-years of follow-up, 469 patients died. Compared with non-normalized BP, normalized BP was associated with an increased risk of all-cause mortality (incidence rates: 60.3 vs 48.5 per 1000/year; HR 1.26; 95% CI 1.04–1.54). Increased risks were observed in patients ≥ 80 years (102.2 vs 77.5 per 1000/year; HR 1.40; 95% CI 1.12–1.74) and with previous cardiovascular events (98.3 vs 63.6 per 1000/year; HR 1.61; 95% CI 1.14–2.27) but not in patients aged 70–79 years (22.6 vs 22.7 per 1000/year; HR 0.83; 95% CI 0.54–1.27) or without previous cardiovascular events (45.2 vs 44.4 per 1000/year; HR 1.16, 95% CI 0.90–1.48).

Conclusion: Blood pressure values below 140/90 mmHg during antihypertensive treatment may be associated with an increased risk of mortality in octogenarians or elderly patients with previous cardiovascular events.

■ Praxisrelevanz

Blutdruckzielwerte gerade bei älteren Patienten mit arterieller Hypertonie sind weiterhin viel diskutiert. Die Ergebnisse dieser prospektiven Kohortenstudie zeigen einen möglichen Zusammenhang auf zwischen Blutdruckwerten $< 140/90$ mmHg und einem erhöhten Mortalitätsrisiko bei Patienten > 80 Jahren bzw. mit kardiovaskulären Vorerkrankungen.

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