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Covered versus bare-metal stenting of the mesenteric arteries in patients with chronic mesenteric ischaemia (CoBaGI): a multicentre, patient-blinded and investigator blinded, randomised controlled trial

Terlouw LG et al. Lancet Gastroenterol Hepatol 2024. https://doi.org/10.1016/S2468-1253(23)00402-8 (Online ahead of print)

Abstract

Background: Mesenteric artery stenting with a bare-metal stent is the current treatment for atherosclerotic chronic mesenteric ischaemia. Long-term patency of bare-metal stents is unsatisfactory due to in-stent intimal hyperplasia. Use of covered stents might improve long-term patency. We aimed to compare the patency of covered stents and baremetal stents in patients with chronic mesenteric ischaemia.

Methods: We conducted a multicentre, patient-blinded and investigator-blinded, randomised controlled trial including patients with chronic mesenteric ischaemia undergoing mesenteric artery stenting. Six centres in the Netherlands participated in this study, including two national chronic mesenteric ischaemia expert centres. Patients aged 18 years or older were eligible for inclusion when an endovascular mesenteric artery revascularisation was scheduled and a consensus diagnosis of chronic mesenteric ischaemia was made by a multidisciplinary team of gastroenterologists, interventional radiologists, and vascular surgeons. Exclusion criteria were stenosis length of 25 mm or greater, stenosis caused by median arcuate ligament syndrome or vasculitis, contraindication for CT angiography, or previous target vessel revascularisation. Digital 1:1 block randomisation with block sizes of four or six and stratification by inclusion centre was used to allocate patients to undergo stenting with bare-metal stents or covered stents at the start of the procedure. Patients, physicians performing follow-up, investigators, and radiologists were masked to treatment allocation. Interventionalists performing the procedure were not masked. The primary study outcome was the primary patency of covered stents and bare-metal stents at 24 months of follow-up, evaluated in the modified intention-to-treat population, in which stents with missing data for the outcome were excluded. Loss of primary patency was defined as the performance of a re-intervention to preserve patency, or 75% or greater luminal surface area reduction of the target vessel. CT angiography was performed at 6 months, 12 months, and 24 months post intervention to assess patency. The study is registered with ClinicalTrials.gov (NCT02428582) and is complete.

Findings: Between April 6, 2015, and March 11, 2019, 158 eligible patients underwent mesenteric artery stenting procedures, of whom 94 patients (with 128 stents) provided consent and were included in the study. 47 patients (62 stents) were assigned to the covered stents group (median age 69·0 years [IQR 63·0–76·5], 28 [60%] female) and 47 patients (66 stents) were assigned to the bare-metal stents group (median age 70·0 years [63·5–76·5], 33 [70%] female). At 24 months, the primary patency of covered stents (42 [81%] of 52 stents) was superior to that of bare-metal stents (26 [49%] of 53; odds ratio [OR] 4·4 [95% CI 1·8–10·5]; p<0·0001). A procedure-related adverse event occurred in 17 (36%) of 47 patients in the covered stents group versus nine (19%) of 47 in the bare-metal stent group (OR 2·4 [95% CI 0·9–6·3]; p=0·065). Most adverse events were related to the access site, including haematoma (five [11%] in the covered stents group vs six [13%] in the bare-metal stents group), pseudoaneurysm (five [11%] vs two [4%]), radial artery thrombosis (one [2%] vs none), and intravascular closure device (none vs one [2%]). Six (13%) patients in the covered stent group versus one (2%) in the bare-metal stent group had procedure-related adverse events not related to the access site, including stent luxation (three [6%] vs none), major bleeding (two (4%) vs none), mesenteric artery perforation (one [2%] vs one [2%]), mesenteric artery dissection (one [2%] vs one [2%]), and death (one [2%] vs none).

Interpretation: The findings of this trial support the use of covered stents for mesenteric artery stenting in patients with chronic mesenteric ischaemia.

Funding: Atrium Maquet Getinge Group.

Praxisrelevanz

Die endovaskuläre Behandlung mittels gecoverten Stents sollte bevorzugt bei der Versorgung von Stenosen und Verschlüssen der Mesenterialgefäße (Truncus coeliacus und A. mesenterica superior) und chronischer Mesenterialischämie durchgeführt werden. Wesentlich ist aber eine enge Indikationsstellung auf Basis einer multidisziplinären Diskussion.

Efficacy and safety of non-vitamin-k antagonist oral anticoagulants versus warfarin across the spectrum of body mass index and body weight: An individual patient data meta-analysis of four randomized clinical trials of 58 464 patients with atrial fibrillation

Patel SM, et al. Circulation 2024; https://doi.org/10.1161/CIRCULATIONAHA.123.066279 (Online ahead of print)

Abstract

Background: The efficacy and safety of non-vitamin-K antagonist oral anticoagulants (NOACs) across the spectrum of body mass index (BMI) and body weight (BW) remain uncertain.
Methods: We analyzed data from COMBINE AF (A Collaboration Between Multiple Institutions to Better Investigate Non-Vitamin K Antagonist Oral Anticoagulant Use in Atrial Fibrillation), which pooled patient-level data from the 4 pivotal randomized trials of NOAC versus warfarin in patients with atrial fibrillation. The primary efficacy and safety outcomes were stroke or systemic embolic events (stroke/SEE) and major bleeding, respectively; secondary outcomes were ischemic stroke/SEE, intracranial hemorrhage, death, and the net clinical outcome (stroke/SEE, major bleeding, or death). Each outcome was examined across BMI and BW. Because few patients had a BMI < 18.5 kg/m² (n = 598), the primary analyses were restricted to those with a BMI ≥ 18.5 kg/m².
Results: Among 58 464 patients, the median BMI was 28.3 (interquartile range, 25.2–32.2) kg/m², and the median BW was 81.0 (interquartile range, 70.0–94.3) kg. The event probability of stroke/SEE was lower at a higher BMI irrespective of treatment, whereas the probability of major bleeding was lower at a higher BMI with warfarin but relatively unchanged across a BMI with an NOAC. NOACs reduced stroke/SEE overall (HR_{adj}, 0.80 [95% CI, 0.73–0.88]; P < 0.001), with a generally consistent effect across BMI (P_{trend} across HR_s, 0.48). NOACs also reduced major bleeding overall (HR_{adj}, 0.88 [95% CI, 0.82–0.94]; P < 0.001), but with attenuation of the benefit at a higher BMI (P_{trend}, 0.003). The overall treatment effects of an NOAC versus warfarin for secondary outcomes were consistent across BMI, with the exception of the net clinical outcome and death, which, although was reduced overall with an NOAC (net clinical outcome, HR_{adj}, 0.91 [95% CI, 0.87–0.95]; P < 0.001; death, HR_{adj}, 0.91 [95% CI, 0.86–0.97]; P = 0.003), tended to favor warfarin at a higher BMI (P_{trend}, 0.001 and 0.08, respectively). This finding was not explained by differences in ischemic or fatal bleeding events. All findings were qualitatively similar when analyzed across BW.
Conclusions: The treatment effect of NOAC versus warfarin in atrial fibrillation is generally consistent for stroke/SEE across the spectrum of BMI and BW, whereas the reduction in major bleeding is attenuated at a higher BMI and BW. Death and the net clinical outcome are reduced with NOACs versus warfarin overall, although there remain uncertainties for these outcomes at a very high BMI and BW.

Praxisrelevanz

Diese große *Post-hoc*-Analyse aus vier randomisierten Studien zeigt einen konsistenten Vorteil von NOAK gegenüber Vitamin-K-Antagonisten über das gesamte Spektrum von Body-mass-Index und Körpergewicht, wobei bei sehr hohen Kategorien die Ergebnisse weniger eindeutig waren. Insgesamt kann auch bei Patienten mit höherem BMI von der Effektivität einer NOAK-Gabe ausgegangen werden.

Universal risk prediction for individuals with and without atherosclerotic cardiovascular disease

Mok Y, et al. J Am Coll Cardiol 2024; 83: 562–73.

Abstract

Background: American College of Cardiology/American Heart Association guidelines recommend distinct risk classification systems for primary and secondary cardiovascular disease prevention. However, both systems rely on similar predictors (eg. age and diabetes), indicating the possibility of a universal risk prediction approach for major adverse cardiovascular events (MACEs).
Objectives: The authors examined the performance of predictors in persons with and without atherosclerotic cardiovascular disease (ASCVD) and developed and validated a universal risk prediction model.
Methods: Among 9,138 ARIC (Atherosclerosis Risk In Communities) participants with (n = 609) and without (n = 8,529) ASCVD at baseline (1996–1998), we examined established predictors in the risk classification systems and other predictors, such as body mass index and cardiac biomarkers (troponin and natriuretic peptide), using Cox models with MACEs (myocardial infarction, stroke, and heart failure). We also evaluated model performance.
Results: Over a follow-up of approximately 20 years, there were 3,209 MACEs (2,797 for no prior ASCVD). Most predictors showed similar associations with MACE regardless of baseline ASCVD status. A universal risk prediction model with the predictors (eg. established predictors, cardiac biomarkers) identified by least absolute shrinkage and selection operator regression and bootstrapping showed good discrimination for both groups (c-statistics of 0.747 and 0.691, respectively), and risk classification and showed excellent calibration, irrespective of ASCVD status. This universal prediction approach identified individuals without ASCVD who had a higher risk than some individuals with ASCVD and was validated externally in 5,322 participants in the MESA (Multi-Ethnic Study of Atherosclerosis).
Conclusions: A universal risk prediction approach performed well in

persons with and without ASCVD. This approach could facilitate the transition from primary to secondary prevention by streamlining risk classification and discussion between clinicians and patients.

Praxisrelevanz

Die präsentierte Studie verfolgt den Ansatz eines universellen Risikobewertungsmodells mit etablierten Prädiktoren für den Einsatz in kardiovaskulärer Primär- und Sekundärprävention. Dies könnte die klinische Routineanwendung erleichtern, muss aber noch in weiteren Studien validiert werden.

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