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AT-VAZ-00220, 05/2025

■ Mortality in randomised controlled trials using paclitaxel-coated devices for femoropopliteal interventional procedures: an updated patient-level meta-analysis

Parikh SA, et al. *Lancet* 2023; Oct. 25, [https://doi.org/10.1016/S0140-6736\(23\)02189-X](https://doi.org/10.1016/S0140-6736(23)02189-X) (Online ahead of print)

Abstract

Background: Numerous randomised clinical trials and real-world studies have supported the safety of paclitaxel-coated devices for the treatment of femoropopliteal occlusive disease. However, a 2018 summary-level meta-analysis suggested an increased mortality risk for paclitaxel-coated devices compared with uncoated control devices. This study presents an updated analysis of deaths using the most complete and current data available from pivotal trials of paclitaxel-coated versus control devices.

Methods: Ten trials comparing paclitaxel-coated versus control devices were included in a patient-level pooled analysis. Cox regression models were used to evaluate the effect of paclitaxel exposure on risk of death in both intention-to-treat (ITT; primary analysis) and three as-treated analysis sets accounting for treatment group crossover

at the index procedure and over time. The effect of paclitaxel dose and baseline covariates were also evaluated.

Findings: A total of 2666 participants were included with a median follow-up of 4.9 years. No significant increase in deaths was observed for patients treated with paclitaxel-coated devices. This was true in the ITT analysis (hazard ratio [HR] 1.14, 95% CI 0.93–1.40), the as-treated analysis (HR 1.13, 95% CI 0.92–1.39), and in two crossover analyses: 1.07 (0.87–1.31) when late crossovers were censored and 1.04 (0.84–1.28) when crossovers were analysed from the date of paclitaxel exposure. There was no significant effect of paclitaxel dose on mortality risk.

Interpretation: This meta-analysis found no association between paclitaxel-coated device exposure and risk of death, providing reassurance to patients, physicians, and regulators

on the safety of paclitaxel-coated devices. Funding Becton Dickinson, Boston Scientific, Cook, Medtronic, Philips, Surmodics, and TriReme Medical.

■ Praxisrelevanz

In Anbetracht dieser Analyse von randomisierten Studien mit deutlich verbesserter Nachbeobachtungsrate sowie einer Vielzahl großer Beobachtungsstudien kann davon ausgegangen werden, dass es kein relevantes Signal für eine erhöhte Langzeit-Mortalität mit Paclitaxel-beschichteten Ballons wie auch Stents nach femoropoplitealen Eingriffen gibt. Auch die US-amerikanische Gesundheitsbehörde (FDA) hat ihren früheren Warnhinweis diesbezüglich im Juli diesen Jahres aufgehoben.

■ Amputation rates and associated social determinants of health in the most populous US counties

Kassavini D, et al. *JAMA Surg* 2023; Nov. 1, e235517. (Online ahead of print)

Abstract

Importance: Social Determinants of Health (SDOH) have been found to be associated with health outcome disparities in patients with peripheral artery disease (PAD). However, the association of specific components of SDOH and amputation has not been well described.

Objective: To evaluate whether individual components of SDOH and race are associated with amputation rates in the most populous counties of the US.

Design, Setting, and Participants: In this population-based cross-sectional study of the 100 most populous US counties, hospital discharge rates for lower extremity amputation in 2017

were assessed using the Healthcare Cost and Utilization Project State Inpatient Database. Those data were matched with publicly available demographic, hospital, and SDOH data. Data were analyzed July 3, 2022, to March 5, 2023.

Main outcome and Measures: Amputation rates were assessed across all counties. Counties were divided into quartiles based on amputation rates, and baseline characteristics were described. Unadjusted linear regression and multivariable regression analyses were performed to assess associations between county-level amputation and SDOH and demographic factors.

Results: Amputation discharge data were available for 76 of the 100 most

populous counties in the United States. Within these counties, 15.3% were African American, 8.6% were Asian, 24.0% were Hispanic, and 49.6% were non-Hispanic White; 13.4% of patients were 65 years or older. Amputation rates varied widely, from 5.5 per 100 000 in quartile 1 to 14.5 per 100 000 in quartile 4. Residents of quartile 4 (vs 1) counties were more likely to be African American (27.0% vs 7.9%, $P < 0.001$), have diabetes (10.6% vs 7.9%, $P < 0.001$), smoke (16.5% vs 12.5%, $P < 0.001$), be unemployed (5.8% vs 4.6%, $P = 0.01$), be in poverty (15.8% vs 10.0%, $P < 0.001$), be in a single-parent household (41.9% vs 28.6%, $P < 0.001$), experience food

insecurity (16.6% vs 12.9%, $P = 0.04$), or be physically inactive (23.1% vs 17.1%, $P < n<0.001$). In unadjusted linear regression, higher amputation rates were associated with the prevalence of several health problems, including mental distress (β , 5.25 [95% CI, 3.66–6.85]; $P < 0.001$), diabetes (β , 1.73 [95% CI, 1.33–2.15], $P < n<0.001$), and physical distress (β , 1.23 [95% CI, 0.86–1.61]; $P < 0.001$) and SDOHs, including unemployment (β , 1.16 [95% CI, 0.59–1.73]; $P = 0.03$), physical inactivity (β , 0.74 [95% CI, 0.57–0.90]; $P < 0.001$), smoking, (β , 0.69 [95% CI, 0.46–0.92]; $P = 0.002$), higher homicide rate (β , 0.61 [95% CI, 0.45–0.77]; $P < .001$), food in-

security (β , 0.51 [95% CI, 0.30–0.72]; $P = 0.04$), and poverty (β , 0.46 [95% CI, 0.32–0.60]; $P < 0.001$). Multivariable regression analysis found that county-level rates of physical distress (β , 0.84 [95% CI, 0.16–1.53]; $P = 0.03$), Black and White racial segregation (β , 0.12 [95% CI, 0.06–0.17]; $P < 0.001$), and population percentage of African American race (β , 0.06 [95% CI, 0.00–0.12]; $P = 0.03$) were associated with amputation rate.

Conclusions and Relevance: Social determinants of health provide a framework by which the associations of environmental factors with amputation rates can be quantified and potentially

used to guide interventions at the local level.

■ Praxisrelevanz

Diese US-amerikanische Analyse unterstreicht den Zusammenhang zwischen sozioökonomischen Risikofaktoren und einem erhöhten Risiko für nicht-traumatisch bedingte Major-Amputationen. Insbesondere Patienten mit kritischer Extremitätenischämie haben oft auch in unserem Gesundheitssystem einen niedrigen sozioökonomischen Hintergrund, was bei der Versorgung jedenfalls berücksichtigt werden sollte.

■ Drug-eluting resorbable scaffold versus angioplasty for infrapopliteal artery disease

Varcoe RL, et al. NEJM 2023; Oct 25, doi: 10.1056/NEJMoa2305637. (Online ahead of print)

Abstract

Background: Among patients with chronic limb-threatening ischemia (CLTI) and infrapopliteal artery disease, angioplasty has been associated with frequent reintervention and adverse limb outcomes from restenosis. The effect of the use of drug-eluting resorbable scaffolds on these outcomes remains unknown.

Methods: In this multicenter, randomized, controlled trial, 261 patients with CLTI and infrapopliteal artery disease were randomly assigned in a 2:1 ratio to receive treatment with an everolimus-eluting resorbable scaffold or angioplasty. The primary efficacy end point was freedom from the following events at 1 year: amputation above the ankle of the target limb, occlusion of the target vessel, clinically driven revascularization of the target lesion, and binary restenosis of the target lesion. The primary safety end point was freedom from major adverse limb

events at 6 months and from perioperative death.

Results: The primary efficacy end point was observed (i.e., no events occurred) in 135 of 173 patients in the scaffold group and 48 of 88 patients in the angioplasty group (Kaplan-Meier estimate, 74% vs. 44%; absolute difference, 30 percentage points; 95% confidence interval [CI], 15 to 46; one-sided $P < 0.001$ for superiority). The primary safety end point was observed in 165 of 170 patients in the scaffold group and 90 of 90 patients in the angioplasty group (absolute difference, -3 percentage points; 95% CI, -6 to 0; one-sided $P < 0.001$ for noninferiority). Serious adverse events related to the index procedure occurred in 2% of the patients in the scaffold group and 3% of those in the angioplasty group.

Conclusions: Among patients with CLTI due to infrapopliteal artery disease, the use of an everolimus-elut-

ing resorbable scaffold was superior to angioplasty with respect to the primary efficacy end point. (Funded by Abbott; LIFE-BTK ClinicalTrials.gov number, NCT04227899.)

■ Praxisrelevanz

Aufgrund der hohen Restenoseraten nach Eingriffen im Bereich der infrapoplitealen Arterien werden hier häufig neue endovaskuläre Behandlungsmöglichkeiten untersucht. Im Gegensatz zu femoropoplitealen Interventionen zeigte sich insbesondere kein Vorteil für Medikamentenbeschichtete Ballons. Für kurze Läsionen werden schon länger Medikamentenfreisetzende Stents verwendet, nun gibt es auch positive Studienergebnisse für bioresorbierbare Everolimus-freisetzende Stents in diesem Bereich.

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