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Titel des Beitrags: Endovascular Therapy Versus Bypass Surgery as First-Line Treatment Strategies for Critical Limb Ischemia: Results of the Interim Analysis of the CRITISCH Registry.

Abstract: The most effective first-line treatment between endovascular therapy and bypass surgery for patients with critical limb ischemia (CLI) is still not well defined. The primary aim of the interim analysis of CRITISCH (Registry of First-Line Treatments in Patients With Critical Limb Ischemia) was to compare both treatment options in a prospective confirmatory manner. Only 1 randomized controlled trial between endovascular therapy and bypass surgery has been published yet. Several retrospective studies showed comparable outcomes between the 2 treatment strategies, but in the majority of them, current endovascular technologies have not been included. Between January 2013
and September 2014, 1,200 CLI patients (Rutherford 4 to 6) from 27 vascular centers were enrolled. The selection of the first-line treatment was left completely to the discretion of the responsible physician. The primary composite endpoint was amputation-free survival (AFS), that is, time to major amputation and/or death from any cause. A pre-specified interim analysis aimed at showing noninferiority of the endovascular therapy versus bypass surgery as to the hazard ratio (HR) of AFS (noninferiority bound = 1.33; interim ? = 0.0058). Time-to-event analyses of major amputation, death, and the composite endpoint of reintervention and/or above-ankle amputation were also conducted. Endovascular therapy was applied to 642 (54%) and bypass surgery to 284 (24%) patients. Median follow-up time was 12 months in both groups. One-year AFS was 75% and 72%, respectively. The noninferiority of endovascular therapy versus bypass surgery for AFS was confirmed (HR: 0.91; upper bound of 1-sided (1 - 0.0058) confidence interval [CI]: 1.29; p = 0.003). An impact of the treatment strategy on time until death (HR: 1.14; 95% CI: 0.80 to 1.63; p = 0.453), major amputation (HR: 0.86; 95% CI: 0.56 to 1.30; p = 0.463), and reintervention and/or above-ankle amputation (HR: 0.89; 95% CI: 0.70 to 1.14; p = 0.348) was not observed. The interim analysis confirmed that when physicians are free to individualize therapy to CLI patients, the endovascular-first approach achieved a noninferior AFS rate compared with bypass surgery. (Registry of First-Line Treatments in Patients With Critical Limb Ischemia [CRITISCH]; NCT01877252).