



Safety and Longer-term Efficacy of Orbital Atherectomy in Patients With Critical Limb Threatening Ischemia and Diabetes Mellitus

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In this post hoc subgroup analysis of prospectively collected data from the observational, multicenter LIBERTY 360 trial, Jammeh et al summarize the outcomes of orbital atherectomy (OA) in 289 patients with chronic critical limb threatening ischemia (CLTI) stratified according to their diabetes mellitus status.¹ Although the study is inherently limited by the lack of randomization and matching of the study cohorts, it provides some important observations.

First, regarding patient characteristics, those without diabetes mellitus were significantly older as compared with patients with diabetes mellitus. This difference in age most likely results from the lack of matching of the study cohorts, but may also be related to the shorter life expectancy of the diabetic patients and/or an earlier manifestation of CLTI in patients with diabetes mellitus.² Rates of obesity, driven by type II diabetes, and chronic kidney disease as one major manifestation of progressive diabetes related organ damage, were significantly higher in patients with diabetes mellitus. Interestingly, no differences were found regarding the prevalence of coronary and cerebral artery diseases.

Second, lesion characteristics show by trend a shorter lesion length (118.3 ± 106.5 mm vs 137.5 ± 128.5 mm) and a significantly lower total occlusion rate (30.8% vs 46.6%) in the diabetic cohort. Both lesion characteristics suggest an overall lower plaque and calcium burden in the lesions treated in the diabetic cohort. Nevertheless, the detected rate of distal embolization was significantly higher in the diabetic subcohort. This may be the result of an impaired microcirculation in patients with diabetes mellitus capturing even small particles deliberated during high-speed orbital atherectomy. Interestingly, this increased periprocedural embolization rate did not result in an increased major adverse event rate, including major amputations; even wound healing rates were comparable. Unfortunately, no information is provided regarding minor amputations.

Third, the study demonstrated that patients with CLTI and diabetes mellitus benefited from orbital atherectomy to the same extent as patients with no diabetes mellitus, which resulted in high rates of limb salvage (93.3% vs 95.8%) and low rates of major adverse events and target-lesion or target-vessel revascularization (TLR/TVR) over a 3-year period. In addition, the 3-year mortality rates of 26.9% and 24.3% for patients with and without diabetes mellitus were well below the previously reported 3-year mortality rates of 40%-60% in patients with CLTI.³ The rates of wound healing are impressive in both patients with and without diabetes mellitus (76.1% vs 77.8% at 1 year and 97.4% vs 100% at 3 years),

which may be the result of first, a close continued outpatient surveillance and follow-up during the prospective study period, and second, a continuous improved wound perfusion with a low TLR/TVR rate at 3-year follow-up.

Randomized controlled trials are mandatory for finally evaluating the real benefit of vessel preparation with orbital atherectomy. OPTIMIZE BTK (Orbital Vessel Preparation to Maximize DCB Efficacy in Calcified Below the Knee Lesions), a small, randomized controlled pilot study, resulted in significantly better primary patency rates at 6 and 12 months of follow-up, if the target lesion was prepared with orbital atherectomy prior to Lutonix 14 drug-coated balloon (BD Bard Medical) angioplasty as compared with vessel preparation with plain balloon angioplasty before drug-coated balloon angioplasty.⁴ However, due to the small sample size, no difference was found in the clinical endpoints including freedom from TLR and major amputation at 1-year follow-up between the 2 study cohorts.

References

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Disclosure: The author has completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Zeller reports institutional grants for research, clinical trial, or drug studies received from Bard Peripheral Vascular, Veyan, Biotronik, Cook Medical, Gore, Medtronic, Philips, Terumo, TriReme, Shockwave, Med Alliance, Intact Vascular, B. Braun, CSI, Boston Scientific, University of Jena, Pluristem, PQ Bypass, Surmodics, Ablative Solutions, and Reflow Medical; consulting fees from Boston Scientific, CSI, Gore, Medtronic, Veyan, Philips-Intact Vascular, Shockwave, Bayer, Vesper Medical, and VentureMed; payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events from Abbott Vascular, BIBA Medical, Biotronik, Boston Scientific, Cook Medical, Gore, Medtronic, Philips-Spectranetics, Shockwave, and Veyan.

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