TCT-569

Prognosis of chronic hemodialysis patients with critical limb ischemia after isolated infrapopliteal balloon angioplasty from the J-BEAT registry

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Background: Clinical outcomes after isolated infrapopliteal angioplasty for critical limb ischemia in patients on hemodialysis (HD) are largely unknown.

Methods: This study obtained the data from multi-center retrospective study: Japan BEAT (Balloon Angioplasty Treatment multi-center registry - J-BEAT registry). In 898 serial patients with 1086 who underwent vascular endovascular therapy for CLI from 2004 to 2010, Subjects were 406 serial patients with 465 limbs who underwent balloon angioplasty for primary treatment of isolated infrapopliteal lesions. Subjects were classified into two groups for comparisons of clinical outcomes: the patients on HD: HD group (242 patients, 283 limbs) and not on HD: non-HD group (164 patients, 182 limbs).

Results: The HD group had a higher percentage of patients with hypertension (83.1 vs. 68.9%, P=0.001), coronary artery disease (60.3 vs. 39.0%, P=0.001), major tissue loss in treated limb (83.0% vs. 73.6%, P=0.014). But, there was no significant statistically difference in the ratio of diabetic patients (69.0 vs. 68.9%). In twelve-month clinical results, there was no statistically difference in the rate of major amputation (19.2 vs. 7.3%) between the two groups. However, the percentage of repeat angioplasty for the treated limb (32.8 vs. 17.5%, p=0.002) and all-caused death (29.5 vs. 14.6%, P=0.003) in the HD group was significantly higher than that in non-HD group. The HD group had a significantly lower rate of freedom from major amputation or all-caused death in about 542±434 days follow-up compared to the non-HD group (logrank test: P<0.001). In multivariate analysis of major amputation in patients on HD, C-reactive protein was more than 3.0 IU/L (p=0.032, 95%CI 1.32-9.95, P=0.001), diabetes mellitus (OR=2.58, 95%CI 1.12-4.61, P=0.024) or smoking (OR=2.32, 95%CI 1.16-4.59, P=0.017) were significant predictors.

Conclusion: More attention should be paid to these risk factors in treating HD patients. Six-month results showed that DB360 outperforms POBA in calcified infrapopliteal arteries.

TCT-570

Six-Month Outcomes of Prospective, Randomized CALCULUM 360 Study Demonstrate the Advantages of Plaque Modification with the Orbital Technology Versus Treatment with Balloon Angioplasty in Patients with Critical Limb Ischemia

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Background: CLI patients frequently present with severely calcified tibial stenoses, resulting in starvation of blood flow to the feet, continuation of limb pain at rest, and exacerbation of nonhealing wounds. Endovascular treatment with the DiamonDBack 360° Orbital PAD System (DB360) may have advantages in modifying calcified lesions to allow lower pressure adjunctive balloon, less need for bailout stenting and improved patient outcomes. This prospective, multi-center, randomized pilot study compares the acute, mid- and long-term outcomes of the DB360 versus plain balloon angioplasty (POBA) in calcified infrapopliteal arteries.

Methods: Fifty subjects were randomized to DB360 (25) or POBA (25). Primary endpoint was acute device success of ≥30% residual stenosis with no dissection type C-F. Symptomatic improvements, revascularization rates and economic data were recorded.

Results: All patients had CLI and calcified infrapopliteal lesions; Rutherford 4 (rest pain) 50%, Rutherford 5 (minor tissue loss) 42%, and Rutherford 6 (major tissue loss) 8%. DB360 arm: 30 lesions; 88.5 mm average lesion length; 135 seconds average device run time; 6.16 atms average max balloon inflation. POBA arm: 35 lesions; 68.5 mm average lesion length; 12.8 atms average max balloon inflation for 112 seconds. Intraprocedural events included 1 (3.3%) dissection for DB360 versus 5 (14.3%) dissections for POBA, 1 (2.8%) perforation and 1 (2.8%) embolization for POBA. Bail-out stenting in 2 (6.7%) DB360 versus 4 (11.4%) POBA lesions. The primary endpoint was met in 93.3% of DB360 versus 76.3% of POBA lesions. Intraprocedural economic data showed cost equivalence between both arms. At six months, no deaths occurred in the DB360 arm versus 4 in the POBA arm. Two major amputations occurred in the DB360 arm versus 3 (1 major, 2 minor) and 1 revisional transcatheter atherosclerosis in the POBA arm. In both arms, ABI improved (1.75 to 0.98), and 82% were reclassified as Rutherford 0-1.

Conclusion: CALCULUM 360 showed that DB360 outperforms POBA in calcified lesions by reducing major dissections and the need for stenting, both major limitations in treating CLI patients. Six-month results showed that DB360 did not increase procedural costs while reducing the ischemic burden of the limb.

TCT-571

Transvenous Intravascular Ultrasound-Guided Endovascular Treatment Of Chronic Total Occlusion Of A Lower Extremity Artery: A Novel Strategy

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Background: In recent years, endovascular treatment (EVT) of chronic total occlusion (CTO) of lower extremity arteries has made major advances with high success rates. Although treatments with duplex echo-guided recanalization, retrograde approaches, and subintimal angioplasty using a re-entry device have advanced, they have some disadvantages. Because of these limitations, safe and reliable methods are required for performing EVT of CTO of lower extremity arteries.

Methods: We performed EVT using the transvenous intravascular ultrasound (IVUS)-guided technique (TIG technique). This technique involves crossing the guidewire through the CTO lesion using images obtained by the IVUS catheter inserted in the vein parallel to the target artery (Figure). In this study, we investigated the primary success rate and complications of EVT using the TIG technique, which was performed in 19 patients with CTO of a lower extremity artery.

Results: Primary success was achieved in all cases using the TIG technique. There were no complications such as guidewire perforation, arterial rupture after balloon dilation or stenting, or venous complications associated with this technique.

A. Left angiographic (fluoroscopy) image. Right, IVUS image from vein.

B. Black circle, triangle, and square are possible locations of guidewires. When the guidewire is at the location of the black circle, we advance the guidewire further. When the guidewire is at the location of the black triangle or square, we do not advance the guidewire further. The guidewire is first pulled back to the previous correct position and subsequently advanced further.

Conclusion: The TIG technique resulted in a higher primary success and lesser complication rates, suggesting that this technique is safe and provides optimal results in EVT of CTO of lower extremity arteries. The TIG technique may be one of the most effective methods in EVT of lower extremity artery occlusive diseases.

TCT-572

Percutaneous Abdominal Aortic Aneurysm Repair: Methods and Initial Outcomes from the First Prospective, Multicenter Trial

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Background: A totally percutaneous approach to endovascular abdominal aortic aneurysm repair (PEVAR) has been shown in multiple single center reports to be feasible. Nonetheless, questions regarding the broader applicability of the approach remain due to the lack of a randomized multicenter trial. We report the methods and outcomes from the roll-in phase of the first prospective, multicenter trial of PEVAR.

Methods: Among 19 institutions participating in the PEVAR Trial (NCT01070069), 38 consecutive patients with abdominal aortic aneurysm were enrolled in a roll-in phase.