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: Critical limb ischemia (CLI) in chronic hemodialysis (HD) patients is associated with high morbidity and mortality. Whether the prognosis of CLI patients in HD is better than in non-HD patients is largely unknown.
Methods: We analyzed the data of patients treated with infrapopliteal angioplasty at 11 institutions in Japan from 2004 to 2010. Subjects were classified into two groups for comparative analysis 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). 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 CLI patients.
Conclusion: The prognosis of CLI patients in HD patients was acceptable at 12 months, but the prognosis was poor in long-term outcomes.

TCT-570
Six-Month Outcomes of Prospective, Randomized CALCIUM 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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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. RFU recovery was 4 (rest pain) 50%, RFU recovery 5 (minor tissue loss) 42%, and RFU recovery 6 (major tissue loss) 8%. DB360 arm: 30 lesions; 88.5 mm average lesion length; 135 seconds average procedure time; 6.18 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. Bailleut 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 recanalization in the POBA arm. In both arms, ABI improved (0.75 to 0.98), and 82% were reclassified as Rutherford 0-1.
Conclusion: After 6 months, DB360 showed to outperform 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 guide wire 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.
Delivered into the vessel adventitia at the treatment site may abate post-intervention inflammation and reduce restenosis rates.

**Methods:** Patients with TASC II A, B, and C disease of the SFA were eligible for this study. Following successful intervention, an adventitial micro-infusion catheter, (Bullfrog®, Mercator MedSystems, San Leandro, Calif.), was advanced over a 0.014” wire to the treated segment. Its micro-needle (0.9 mm long x 140 μm diameter) was deployed into the adventitia to deliver dexamethasone (DEX, 4 mg/ml) mixed with iodixanol contrast agent (80:20 ratio), providing fluoroscopic visualization. In total, 5 mg of DEX was infused per 5 cm of treated artery.

**Results:** Six patients have been enrolled in this study (mean age, 66 years). Mean lesion length was 88 mm and included 3 TASC II As, 2 Bs, and 1 C lesion (4-6 were chronic total occlusions). Each case resulted in complete cylindrical distribution of DEX in the adventitia around the target artery with 100% technical success and no adverse events, Table 1. Treatment required an average of 2.7 injections per patient.

**Conclusion:** Adventitial drug delivery is a feasible alternative to luminal or intimal delivery modes. The micro-infusion catheter is a safe and efficient method to achieve adventitial drug delivery. Further study is warranted to determine if DEX treatment of the SFA decreases restenosis rates.