TCT-P521

Impact of tibial artery calcification pattern on the outcomes of below the knee intervention.

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Background: Tibial artery calcification (TAC) has been reported to be associated with increased risk of amputation. However, there are little available data on the outcomes after below the knee (BTK) intervention according to the severity of TAC. In this study, we aimed to investigate the relationship of the TAC pattern with outcomes of BTK intervention.

Methods: We reviewed medical records of 109 patients (112 lesions) who underwent a lower extremity CT angiography before BTK intervention from April 2008 to May 2013. Major adverse limb event (MALE) was defined as any re-intervention or unplanned amputation of the index limb. TAC severity patterns were classified into three patterns based on the images of maximum intensity projection of lower extremity computed tomography angiogram; no evidence of calcification (38), patchy pattern (44) or linear pattern (30) of calcification.

Results: Mean age of total subjects was 68.8 ± 11.7 years. Male proportion was 85% (96). Patchy and linear pattern groups had higher prevalence of diabetes mellitus and higher Rutherford scores than no calcium group (p<0.001, 0.002). Prevalence of chronic kidney disease was the highest in linear pattern following patchy and no calcium (63.3%, 36.4%, and 23.7%, respectively, p=0.004). More BTK run-offs were observed in the linear pattern (p=0.024). However, technical success and complications of BTK intervention did not differ according to the groups. Total 28 cases of unplanned major and minor amputations were evident during mean 2.5 years follow up; 5 (13.2%) cases in the no calcium, 9 (20.5%) in the patchy calcification, and 14 (46.7%) in the linear calcification (p=0.04). There was no difference of MALE between the groups (p=0.31). After multivariate analysis, Rutherford score and suboptimal intervention were related to the unplanned amputation (HR 2.4, 95% CI 1.31-4.6; HR 2.3, 95% CI 1.1-5.0).

Conclusions: Linear pattern TAC was related higher rate of amputation after BTK intervention. This result may be related to higher baseline Rutherford score.

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Outcomes of Laser-Assisted Balloon Angioplasty versus Balloon Angioplasty Alone for Below Knee Peripheral Arterial Disease

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Background: Laser-assisted balloon angioplasty (LABA) has been shown to be more effective in achieving angiographic success for endovascular treatment for below knee peripheral artery disease. However, long-term outcomes of LABA compared with balloon angioplasty alone (BA) for popliteal and infra-popliteal arterial intervention are not known.

Methods: We evaluated data on 731 patients (pts) undergoing LABA (n=398) and BA (n=333) retrospectively at a single center (2007-2012). Outcomes included ipsilateral major limb amputation, revascularization and death at a median follow up of 35.5 months.

Results: Baseline features were similar in 2 groups with the exceptions of more LABA pts having TASC-D lesions (92.5 vs. 66.7 %; p<0.0001) and chronic total occlusions (64.6 vs. 49.5 %; p<0.0001). Angiographic success was higher in LABA compared with BA (97.6% vs. 89.2 %; p<0.0001). Ipsilateral limb amputation was similar LABA and BA pts (7.3% vs. 8.1%, p=0.64) despite unfavorable baseline characteristics in the former. Independent predictors of major limb amputation included diabetes (HR 5.52, 95% CI 1.8-16.7), prior contralateral limb amputation (HR 2.24, 95% CI 1.0-5.0) and Total pre-procedural Yamasaki score (HR 1.2, 95% CI 1.1-1.4). Repeat ipsilateral revascularization was also similar in the LABA and BA pts (23.9% vs. 22.2%, p=0.56). Independent predictors of repeat revascularization included prior peripheral bypass surgery (HR 1.64, 95% CI 1.0-2.7), stroke (HR 1.44, 95% CI 1.0-2.0), diabetes (HR 1.42, 95% CI 1.0-1.9) and total pre-procedural Yamasaki score (HR 1.14, 95% CI 1.1-1.2). Death occurred 140 (35.2%) and 88 (26.4%) pts in LABA and BA respectively, reflecting the worse baseline characteristics of the LABA group.

Conclusions: LABA achieved higher angiographic success and similar ipsilateral major amputation and revascularization rates despite unfavorable baseline characteristics compared with BA pts. However, despite greater angiographic success, LABA did not appear to be associated with improved long-term mortality, suggesting that comorbidities rather than angiographic success are the key driver of death in pts undergoing below knee interventions.

TCT-P523

Therapeutic Potential Of Sustained Release Sodium Nitrite For Critical Limb Ischemia In The Setting Of Metabolic Syndrome

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Background: The pursuit of treatments for critical limb ischemia (CLI) remains a priority due to the devastating implications of this disease. Nitric oxide (NO)-based therapies have emerged as effective treatments for ischemic injury by promoting vasodilation and angiogenesis and by prevention of tissue necrosis. We investigated a novel sustained release formulation of nitrite (SR-Nitrite) in a clinically relevant swine model of CLI involving metabolic syndrome (MetS).

Methods: Obese Ossabaw miniswine (n=18) were subjected to percutaneous implantation of a covered stent in combination with an Amplator occluder in the external iliac to induce CLI. At 14 days following CLI pigs were randomized to placebo (n=9) or SR-Nitrite (n=9) therapy for 21 days. Plasma and skeletal muscle were collected for molecular analysis and NO measurements.

Results: SR-Nitrite therapy increased plasma and skeletal muscle nitrite and N-Nitrosothiol levels at 35 days post-CLI. Analysis of VEGF and markers for endothelial cell proliferation (CD31 and vWF) revealed that SR-Nitrite promoted angiogenic signaling in the ischemic limb. SR-Nitrite also significantly reduced oxidative stress in the ischemic limb. However, we failed to observe improvement in Ankle Brachial Index (ABI) or collateral vessel growth measured by angiography.

Conclusions: In a clinically relevant model of MetS and CLI, SR-Nitrite treatment restored NO levels, induced angiogenic signaling, and reduced ischemic limb oxidative stress. However, nitrite failed to improve lower limb blood flow and promote large vessel collateralization.

TCT-P524

Physiologic Guidance of Infragingual Vascular Interventions Using the Pressure Wire

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Background: The role of measuring transluminal pressure gradients (TLG) via pressure wire during infragingual vascular interventions is not well understood. This study seeks to evaluate the relationship between resting and hyperemic TLG (RG, HG) and in-lesion peak systolic velocity (PSV-L), PSV-L to pre-lesion PSV ratio (PSV-R), measured by Duplex US, and ankle-brachial index (ABI) before and after an intervention.

Methods: In 25 patients with focal infragingual arterial stenosis, TLG at rest (RG) and after hyperemia (HG) were measured via a pressure wire before and after an intervention.

Results: Mean age was 73±12 years, 70% were men, median Rutherford class 3. At baseline and after the angioplasty, mean ABI was 0.78±0.1, mean PSV-L was 459±110mm/sec and 126±35 m/sec, and mean PSV-R was 67±4 and 1.2±0.5 respectively. RG and HG significantly improved (p<0.001) from baseline to after angioplasty (29±20 to 5±13 mm Hg, and 401±21 to 10±13 mmHg respectively).

The correlations between the TLG’s and PSV-L, PSV-R, and ABI’s, as well as the change in TLG versus the change in PSV-L, PSV-R, ABI before and after angioplasty are shown in the table.
Conclusions: The resting gradient (RG) and hyperemic gradient (HG) measured via the pressure wire showed an excellent correlation with the established markers of stenosis severity (PSV-L, PSV-R, and ABI) both prior as well as after angioplasty. Moreover, the improvement in RG and HG after angioplasty strongly correlated with the improvement in PSV-L, PSV-R, and ABI. Therefore, pressure wire can be an excellent tool to guide infragenital vascular interventions.

TCT-525
Wound depth assessed by Texas grade affect wound healing in critical limb ischemia after endovascular therapy
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Background: Wound depth assessment by Texas classification is important for diabetic foot. We evaluated wound depth in patients with critical limb ischemia (CLI) with tissue loss and investigated wound healing.

Methods: Between April 2007 and January 2013, consecutively 177 patients (225 limbs) who received endovascular treatment for CLI with tissue loss were enrolled in this study. In these limbs, 236 individual wounds existed and we evaluated their wound depth by Texas classification. Wound depth was divided into three groups: grade 1 (superficial wound not involving tendon, capsule, or bone; n=90); grade 2 (wound penetrating to tendon or capsule; n=111); and grade 3 (wound penetrating bone or joint; n=35). Study primary end point was wound healing rate and secondary end point was time to wound healing.

Results: At 3, 6, 9, and 12 months, wound healing rate was 58%, 73%, 86%, and 86%, respectively in grade 1; 23%, 34%, 47%, and 45%, respectively in grade 2; 11%, 15%, 17%, and 23%, respectively in grade 3. Kaplan-Meier analysis revealed statistically significant differences between the 3 groups (p<0.001). The median time to healing was 65 days (interquartile range 25-142 days); 131 days (66-239 days), and 148 days (74-255 days), respectively between the 3 groups (p=0.007).

Conclusions: The severity of wound depth affect poor wound healing in CLI.

TCT-526
The Impact of Wound Healing for Isolated Below the Knee Lesion Patients with Critical Limb Ischemia
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Background: Endovascular treatment (EVT) has recently developed as a choice of treatment for critical limb ischemia (CLI). On the other hand, isolated below the knee (BK) lesion patients are still poor prognosis of wound healing. The impact of wound healing for these patients is unknown.

Methods: A multicenter study was conducted to evaluate the clinical outcomes of 314 Japanese critical limb ischemia patients. Of these, 109 isolated BK lesion patients who underwent EVT and have tissue loss (Rutherford 5, 6) were enrolled. Patients were enrolled from December 2009 to July 2011 and were followed-up for 12 months. We analyzed the predictor for the wound healing and its interval. This study was performed as a sub-analysis of OLIVE (EndOvascarL Treatment for Infragenital Vessels) Registry.

Results: In 109 patients, age was 71±10.1 years old and Rutherford classification was 5.1±0.3. As 18 subjects died in 12 months, follow-up period was 9.9±3.7 months. Eighty nine patients’ wound was healed and wound healing interval was 4.3±3.1 months. Number of treated BK vessels (1.6±0.6 vessels) was not corrected (p-value=0.83, odds ratio=1.12, 95% CI=0.72-1.73) with wound healing. In addition, 107 patient were established one straight line and it was no statistical significance (p-value=0.69, odds ratio=1.50, 95% CI=0.21-10.8) with wound healing.

The predictors of wound healing were renal failure (p-value=0.02, odds ratio=0.61, 95% CI=0.30-0.90) and Rutherford 6 (p-value=0.05, odds ratio=0.47, 95% CI=0.22-1.03). The result of this study suggested that only baseline clinical characteristics were the predictor of wound healing in critical ischemia patients.

TCT-527
Obtainment of Wound Blush is The Most Important Angiographic Endpoint For Wound Healing
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Background: Several reports have been published of the acceptable patency and limb salvage rates following infra-popliteal interventions for the treatment of critical limb ischemia (CLI). However, the optimal angiographic endpoint of endovascular therapy (EVT) remains unclear. The aim of this study was to assess the relationship between the appearances of wound blush as an angiographic endpoint and wound healing in patients with CLI.

Methods: “Wound blush” was defined as contrast opacification of the vessels around the wound in final angiography of EVT through the catheter introduced into the popliteal artery. We analyzed the data of 185 limbs with ischemic ulcerations classified as Rutherford category 5 or 6, who underwent EVT alone, without bypass surgery. Patients were divided into two groups depending on whether or not wound healing was achieved.

Results: The overall wound healing rate was 73.5%. The rate of positive wound blush, patency of planter artery and the number of patent below the ankle vessels were significantly higher in the wound healing group than in no wound heal group. In the multivariate analysis, obtainment of wound blush was independent predictor for wound healing.

Conclusions: Presence of wound blush after EVT is associated with wound healing. Wound blush as an angiographic endpoint in EVT may be a novel predictor of wound healing in patients with CLI.

TCT-528
Differences in Long-term Outcomes After Endovascular Therapy for Femoropopliteal Artery Disease in Critical Limb Ischemia Patients With and Without Chronic Heart Failure
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Background: Clinical outcomes of endovascular therapy (EVT) for critical limb ischemia (CLI) patients with chronic heart failure (CHF) has not well investigated in real-world setting. The aim of this study is to examine differences in long-term outcomes after EVT for femoropopliteal artery disease in CLI patients with and without CHF.

Methods: From January 2004 to December 2011, a retrospective analysis was conducted of data from 13 Japanese cardiovascular centers. 899 CLI patients(104 limbs,59.0% men,165 patients with CHF:73.5% 02 years old) underwent EVT for de novo femoropopliteal lesions. The primary outcome measure was amputation-free survival(AFS). The secondary outcome measures were overall survival, limb salvage rate, freedom from major adverse cardiovascular events (MACE; all-cause death, myocardial infarction and stroke) and freedom from major adverse limb events (MALE; includes any repeat revascularization and major amputation). Mean follow-up was 2.1±2.1 months.

Results: The AFS, overall survival, freedom from MACE and freedom from MACE rate at 4 years were significantly lower in the CHF group(42.0% vs 53.7% P=0.001, 46.9% vs 58.2% P=0.001, 34.8% vs 54.2% P=0.002 40% vs 54.9% P=0.001). Limb salvage rate was no significant difference between the groups. After correcting all end points with baseline variables, CHF was effective for worsening AFS (hazard ratio [HR], 1.42; 95% confidence interval [CI], 1.02-1.95; adjusted P=0.03) and freedom from MACE (hazard ratio [HR], 1.47 95% confidence interval [CI], 1.07-201; adjusted P=0.01). The others were no significant differences between the groups.

Conclusions: Chronic heart failure may worsen the AFS, and freedom from MACE after EVT for femoropopliteal artery disease in critical limb ischemia patients. CHF may be a risk factor for patients with critical limb ischemia.