

Conclusions: Greater concentrations of CD40L and TNF-B were seen at the site of stenosis and may promote inflammation in symptomatic SFA disease. A local inflammatory response is particularly notable in newly diagnosed, symptomatic patients not currently taking aspirin, clopidogrel or a statin.

TCT-158

Impact Of Subclinical Peripheral Arterial Disease Severity On Middle And Long Term Outcomes In Patients With ST-Elevation-Myocardial Infarction

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Background: The presence of clinical peripheral arterial disease (PAD) is associated with an increased risk of adverse cardiovascular outcomes among patients with coronary artery disease (CAD). However, there is little data regarding the impact of the presence and degree of the subclinical PAD on outcomes in patients with CAD, specially those that undergoing percutaneous coronary intervention (PCI) for ST-elevation-myocardial infarction (STEMI). We aimed to assess prospectively the grade of subclinical PAD in the setting of patients that undergoing primary PCI for prediction of middle and long-term clinical outcomes.

Methods: A total of 971 consecutive patients without history of clinical PDA that undergoing primary PCI for STEMI were included in a prospective follow-up. Subclinical PAD severity was blindly assessed based on a previously described ultrasound arterial morphology classification (UAMC) defined with an high-resolution ultrasound assessment of wall carotid and femoral artery bifurcations. This classification included four classes (I: normal, II: wall thickening, III: non-stenosing plaques, IV: stenosing plaques) corresponding to four scores ranging between 2 and 8 for each artery (total score from 8 to 32 in each patient). The group was divided into four classes according to UAMC and each patient was assigned a score. We evaluated death, and major cardiovascular and cerebrovascular events after 40 months' mean follow-up.

Results: At multivariable analysis, mortality in class IV group was more than 16-fold higher (hazard ratio [HR], 16.50; 95% confidence interval [CI], 7.76 to 35.07; $P < 0.001$) when compared with the class I group and was also increased in the class III group (HR, 4.47; 95% CI, 2.55 to 8.76; $P < 0.001$) and class II group (HR, 1.62; 95% CI, 1.30 to 2.18; $P < 0.05$). Similarly, an increasing effect was seen across UAMC strata for MACCE in the class IV group (HR, 12.29; 95% CI, 9.16 to 16.50; $P < 0.001$), class III group (HR, 11.70; 95% CI, 8.54 to 16.24; $P < 0.001$), and class II group (HR, 1.92; 95% CI, 1.40 to 2.55; $P = 0.005$).

Conclusions: The UAMC may be applied in the STEMI population that undergoing primary PCI and is able to stratify patients for poor middle and long term clinical outcomes.

TCT-159

Effects of PRT-201, a Recombinant Human Type I Pancreatic Elastase, Treatment on the Elastin Content and Compliance of Atherosclerotic Tibial Arteries Following Ex Vivo Angioplasty

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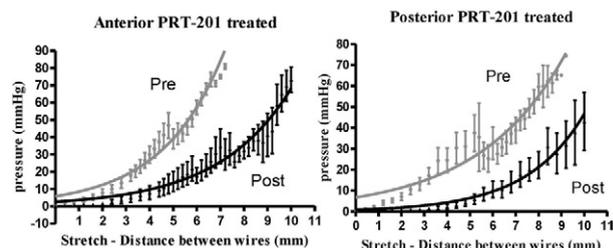
Background: At physiologic pressures, the elastin fiber network constrains artery diameter. Fragmenting elastin fibers following successful angioplasty of atherosclerotic arteries could result in larger artery lumen diameter and area. The purpose of this study was to investigate the use of PRT-201, a recombinant human type I pancreatic elastase, as an adjuvant therapy to balloon angioplasty for treatment of peripheral artery disease (PAD).

Methods: Diseased tibial arteries were harvested from patients undergoing lower limb amputations for PAD. Ex vivo balloon angioplasty was performed using a balloon chosen to match the lumen diameter of the artery taken at the intima-plaque interface. Thereafter, the arteries were cut into 6 x 1.5 mm rings and studied on a wire myograph to obtain baseline compliance data. Then the external surface of the artery was bathed in PRT-201 2 mg/mL or saline for 60 minutes and myography was repeated. Treated rings were

analyzed for desmosine (elastin) content by RIA and elastin fiber staining by histology. Desmosine is a protein cross-link unique to elastin.

Results: PRT-201 but not saline caused a shift in the compliance curve of artery rings from the anterior and posterior tibial arteries (Figure) associated with an increases in lumen diameter and area across a range of pressures. PRT-201 treatment reduced desmosine (elastin) content by 60% and reduced elastin fiber staining on histology.

Conclusions: The results suggest that PRT-201 treatment following balloon angioplasty of atherosclerotic arteries could increase artery lumen diameter and area without requiring placement of a stent.



TCT-160

Effects of PRT-201, a Recombinant Human Type I Pancreatic Elastase, Treatment on the Elastin Content and Compliance of Atherosclerotic Tibial Arteries Using a Perfusion Myograph

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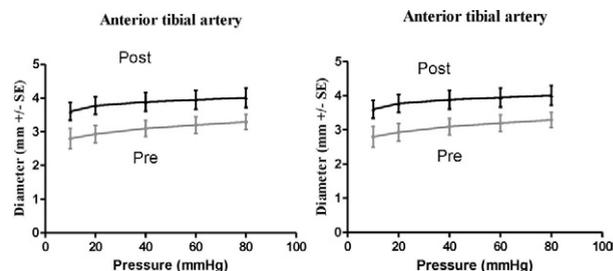
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Background: At physiologic pressures, elastin fibers constrain artery diameter. Removing elastin fibers from an atherosclerotic artery could result in larger artery lumen diameter and greater blood flow. The purpose of this study was to investigate the use of PRT-201 as a treatment for peripheral artery disease (PAD).

Methods: Anterior and posterior tibial arteries were obtained within 24 hrs of death from persons who donated their bodies to science. The arteries were visually atherosclerotic. 3-4 cm long segments of artery were mounted onto the perfusion myograph and bathed in Krebs solution at 37C gassed with a mix of 95% O₂/ 5% CO₂. Transmural pressures were increased from 10 to 80 mmHg while diameter was continuously recorded to create a compliance curve. Then PRT-201 was applied at a concentration of 3.6 mg/mL for 30 min and the compliance curve was repeated. The artery was analyzed for elastin content by desmosine radioimmunoassay (RIA). Desmosine is a protein cross-link unique to elastin.

Results: 6 donors provided 10 tibial arteries. The figure displays the compliance curves for the tibial arteries pre- and post-PRT-201. Average anterior tibial artery diameter increased by 0.78 ± 0.21 mm ($27 \pm 12\%$) and average posterior tibial artery diameter increased by 0.58 ± 0.30 mm ($21 \pm 11\%$), all $p < 0.001$, following PRT-201 treatment. PRT-201 reduced elastin content measured by desmosine RIA by approximately 50%.



Conclusions: PRT-201 treatment removed elastin from atherosclerotic tibial arteries and altered artery compliance so as to increase artery diameter.

TCT-161

Long term effect of transcatheter intra-arterial administration of bone marrow mononuclear cells in patients with critical limb ischemia

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Background: Therapeutic vasculogenesis in patient with critical limb ischemia (CLI) is an experimental method with good short term results. Successful vasculogenesis is achieved by transcatheter intra-arterial administration of autologous bone marrow mononuclear cells (BMMC) directly into the ischemic foot. However, the longterm effects of