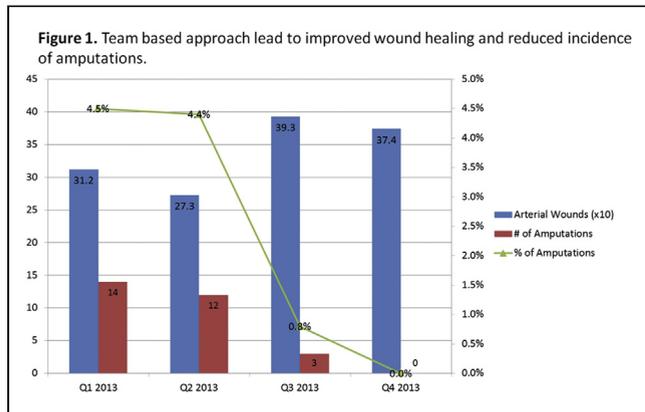


these patients healed within 25 days and the palliative patient population decreased by 40%.

**CONCLUSION** Creating a multi-disciplinary team dedicated to peripheral arterial disease (PAD) awareness and a limb preservation program leads to improved arterial wound heal rates and lower amputation rates. These results support the idea that the standard of care for CLI patients should mandate an immediate referral to a CLI program with an evaluation by a vascular specialist upon detection of a new wound. Therefore, vascular surgeons and endovascular specialists can play an important role in the formal wound care setting.



**CRT-300.06**  
**Efficacy and Histomorphologic Evaluation of a Novel Large Bore Vascular Closure Device in Swine**

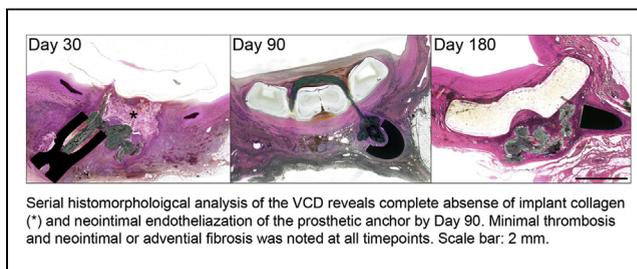
Kenta Nakamura,<sup>1</sup> Lynn Bailey,<sup>2</sup> Todd Grintz,<sup>3</sup> John Keating,<sup>2</sup> Elazer R. Edelman<sup>4</sup>  
<sup>1</sup>Massachusetts General Hospital, Boston, MA; <sup>2</sup>CBSET Inc., Lexington, MA; <sup>3</sup>Essential Medical, Inc., Malvern, PA; <sup>4</sup>Massachusetts Institute of Technology, Cambridge, MA

**BACKGROUND** Vascular access site complications are a significant source of morbidity following percutaneous catheterization, particularly for interventions requiring large bore cannulation such as transcatheter aortic valve replacement (TAVR). The benefit of vascular closure device (VCD) over manual compression is most pronounced for large bore access and higher baseline risk. We report a novel vascular closure device (VCD) that utilizes a collagen implant secured by intraluminal anchor and is specifically designed for large bore cannulation.

**METHODS** Three Yorkshire swine underwent surgical laparotomy to expose the abdominal aorta. Three 18 French vascular access sites were obtained in each animal and closed with the VCD. Angiography was performed on Days 0, 15 and prior to necropsy. Limited necropsy was performed at Days 30, 90, and 180 for histomorphological analysis.

**RESULTS** All nine VCD deployments achieved patent hemostasis on first attempt as assessed by gross inspection and angiography. Serial histomorphological analysis revealed complete dissolution of implant collagen and presence of neointimal endothelialization of the prosthetic anchor by Day 90 day (Figure). Histological evidence of thrombosis was minimal at Day 30 and subsequently absent thereafter, and neointimal or adventitial fibrosis was minimal at all timepoints. There was no evidence of vascular occlusion or other complication at anytime.

**CONCLUSION** The novel VCD successfully closed large bore arterial access in swine without complication and favorable healing characteristics as assessed by serial histomorphology. This VCD is a promising platform for rapid, effective, and safe large bore arterial closure.



**CRT-300.07**  
**The Association of Cardiac Valve Sclerosis With Clinical Outcomes in Patients Undergoing Endovascular Revascularization for Peripheral Arterial Disease**

Ji Young Park,<sup>1</sup> Seung-Woon Rha,<sup>2</sup> Byoung Geol Choi,<sup>2</sup> Se Yeon Choi,<sup>2</sup> Sang-Ho Park,<sup>3</sup> Ji Yeon Hong<sup>4</sup>  
<sup>1</sup>Eulji General Hospital, Seoul, Korea, Republic of; <sup>2</sup>Korea University Guro Hospital, Seoul, Korea, Republic of; <sup>3</sup>Soonchunhyang University Cheonan Hospital, Cheonan, Korea, Republic of; <sup>4</sup>KEPCO medical center, Seoul, Korea, Republic of

**BACKGROUND** Peripheral arterial disease (PAD) is known to be associated with poor outcomes and cardiac valve sclerosis (CVS) is reported to be associated with future cardiovascular events. We evaluated the association of CVS with the clinical outcomes in patients (pts) with PAD who underwent percutaneous transluminal angioplasty (PTA).

**METHOD** The outcomes of 298 consecutive pts with symptomatic PAD who underwent PTA were enrolled for analysis. Study populations were divided into two groups; PAD with CVS (n=41) and PAD without CVS (n=257). CVS (Aortic or mitral valve sclerosis) is defined as calcification and thickening of leaflets in aortic or mitral valve in the absence of obstruction of ventricular outflow. The incidence of restenosis, amputation rates and clinical outcomes were assessed at a follow-up of 2 years.

**RESULTS** Pts with CVS had higher incidence of wounds as the initial diagnosis for PAD (80.5% vs. 56.0%, p=0.003), diabetes mellitus (92.7% vs.70.8%, p=0.002), hypertension (87.8% vs. 67.3%, p=0.009), chronic kidney disease (43.9% vs. 23.0 %, p=0.007), need for dialysis (34.1% vs. 16.0%, p=0.009), and previous history of percutaneous coronary intervention (26.8% vs. 13.6%, P=0.037). At 8 months follow-up, patients with CVS had higher rate of total occlusion of the limb (83.3% vs. 33.6%, p=0.023). At 2-year follow up, the incidence of repeat PTA and major adverse cardiovascular events (MACE) was similar between the two groups, but the pts with CVS had higher amputation rate (39.3% vs. 15.6%, p=0.005).

**CONCLUSION** In this study, patients with CVS had more frequently presented with critical limb ischemia, higher rates of total occlusion and amputation rate at 2 years following successful PTA compared with those of PAD without CVS. More intensive therapies will be needed for this particular subset of risky patients.

**CRT-300.08**  
**The Impact of Current Smoking on Clinical outcomes in Peripheral Arterial Disease Patients undergoing Endovascular Revascularization**

Ji Young Park,<sup>1</sup> Seung-Woon Rha,<sup>2</sup> Byoung Geol Choi,<sup>2</sup> Se Yeon Choi,<sup>2</sup> Sang Ho Park,<sup>3</sup> Ji Yeon Hong<sup>4</sup>  
<sup>1</sup>Eulji General Hospital, Seoul, Korea, Republic of; <sup>2</sup>Korea University Guro Hospital, Seoul, Korea, Republic of; <sup>3</sup>Soonchunhyang University Cheonan Hospital, Cheonan, Korea, Republic of; <sup>4</sup>KEPCO medical center, Seoul, Korea, Republic of

**BACKGROUND** Peripheral arterial disease (PAD) is known to be associated with poor outcomes. However, the impact of smoking on major clinical outcomes following percutaneous transluminal angioplasty (PTA) is not clear yet.

**METHODS** The 559 consecutive symptomatic PAD patients (pts) who underwent PTA were enrolled for this analysis. The incidence of restenosis, amputation rate and repeat revascularization were

assessed between the current smoker (n=177) and non-smokers (n=382) in significant PAD (pts) who underwent PTA at 1 year.

**RESULTS** Current smokers had more male gender (96.0% vs. 69.4%,  $p<0.01$ ), whereas non-smokers had a higher incidence of hypertension (63.3% vs. 72.8%,  $p=0.029$ ), diabetes mellitus (68.4% vs. 76.7%;  $P=0.039$ ), cerebral vascular disease (11.3% vs. 20.2%,  $p=0.011$ ), chronic kidney disease (22.0% vs. 31.2%;  $p=0.027$ ), need for dialysis (11.9% vs. 22.8%;  $p=0.003$ ), coronary artery disease (48.0% vs. 59.2%,  $p=0.017$ ). Wounds as the initial diagnosis were higher in non-smoker group (55.9% vs. 68.6%,  $p=0.004$ ), but ischemic resting pain as the initial diagnosis was high in current smoker group (21.5% vs. 9.7%  $p<0.01$ ). PTA at iliac artery (36.2% vs. 20.2%,  $p<0.01$ ), femoral artery (21.5% vs. 13.1%,  $p=0.017$ ), and below the knee (60.5% vs. 72.8%,  $p=0.004$ ) was more commonly performed in the current smokers. At 8 months, non-smokers had higher rate of total occlusion of the limb (35.1% vs. 50.8%,  $p=0.039$ ). At 1-year, the incidence of repeat PTA, amputation rate, and major adverse cardiovascular events (MACE) were similar between the two groups.

**CONCLUSION** Although current smokers had lower incidence of traditional cardiovascular risks, more frequently presented with critical limb ischemia and had higher rates of PTA compared with symptomatic PAD with non-smokers. Despite of expected worse outcomes in smokers, smoking itself did not negatively impacted on the 1-year incidence of repeat PTA and amputations rates following successful PTA.

#### CRT-300.09

##### Percutaneous Coronary Intervention versus Optimal Medical Therapy in Peripheral Arterial Disease Patients Underwent Endovascular Revascularization and Combined With Significant Coronary Artery Disease

Ji Young Park,<sup>1</sup> Seung-Woon Rha,<sup>2</sup> Byoung Geol Choi,<sup>2</sup> Se Yeon Choi,<sup>2</sup> Sang Ho Park,<sup>3</sup> Ji Yeon Hong<sup>4</sup>

<sup>1</sup>Eulji General Hospital, Seoul, Korea, Republic of; <sup>2</sup>Korea University Guro Hospital, Seoul, Korea, Republic of; <sup>3</sup>Soonchunhyang University Cheonan Hospital, Cheonan, Korea, Republic of; <sup>4</sup>KEPCO medical center, Seoul, Korea, Republic of

**BACKGROUND** Peripheral arterial disease (PAD) is known to be associated with poor outcomes due to higher incidence of combined cardiovascular morbidity and mortality. We evaluated the clinical outcomes of patients (pts) who underwent peripheral transluminal angioplasty (PTA) for PAD with combined significant coronary artery disease (CAD) treated by percutaneous coronary intervention (PCI) versus optimal medical therapy (OMT).

**METHODS** The outcomes of 311 consecutive pts with symptomatic PAD who underwent PTA were enrolled for the analysis. Pts were divided into two groups; 1) PAD with CAD underwent PCI (N=154) and 2) PAD with CAD treated with OMT (N=157). The incidence of restenosis, amputation rates and clinical outcomes were compared between the two groups up to 1 year.

**RESULTS** PAD pts with CAD underwent PCI had suffered from more chronic kidney disease (CKD, 35.1% vs. 22.8%;  $p=0.024$ ) and myocardial infarction (MI, 20.8% vs. 1.9%;  $p<0.001$ ). The incidence of claudication (20.1% vs. 6.4%;  $p<0.001$ ) and gangrene (32.5% vs. 15.9%;  $p=0.001$ ) as the initial diagnosis for PAD were higher in pts with CAD underwent PCI. At 8 months follow-up, the incidence of binary restenosis, total occlusion of the limb were similar between the two groups. However, at 1-year follow up, the incidence of repeat PTA (8.7% vs. 18.0%;  $P=0.025$ ) and below knee amputation rate (12.3% vs. 20.7%;  $p=0.060$ ) were lower in pts with CAD underwent PCI. Major adverse cardiovascular events (MACE) were similar between the two groups.

**CONCLUSION** PAD pts underwent PCI had higher comorbidity including CKD and MI, and more frequently presented with critical limb ischemia. However, the incidence of restenosis and amputation rate at 1 years were lower in CAD pts underwent PCI, suggesting there may be significant risk reduction by PTA and PCI compared with control group.

#### CRT-300.10

##### The Impact of the Use of Renin Angiotensin Aldosterone Blocker on Clinical Outcomes in Patients Undergoing Endovascular Revascularization for Peripheral Arterial Disease

Ji Young Park,<sup>1</sup> Seung-Woon Rha,<sup>2</sup> Byoung Geol Choi,<sup>2</sup> Se Yeon Choi,<sup>2</sup> SangHo Park,<sup>3</sup> Ji Yeon Hong<sup>4</sup>

<sup>1</sup>Eulji General Hospital, Seoul, Korea, Republic of; <sup>2</sup>Korea University Guro Hospital, Seoul, Korea, Republic of; <sup>3</sup>Soonchunhyang University Cheonan Hospital, Cheonan, Korea, Republic of; <sup>4</sup>KEPCO medical center, Seoul, Korea, Republic of

**BACKGROUND** Peripheral arterial disease (PAD) is known to be associated with poor outcomes due to higher incidence of combined cardiovascular morbidity and mortality. We evaluated the impact of the use of renin-angiotensin-aldosterone (RAS) blocker on clinical outcomes in patients (pts) with PAD who underwent percutaneous transluminal angioplasty (PTA).

**METHOD** The outcomes of 559 consecutive pts with symptomatic PAD who underwent PTA were enrolled for analysis. Pts were divided into two groups according to use of RAS blocker; PAD with RAS blocker (n=309) and PAD without RAS blocker (n=250). The incidence of restenosis, amputation rates and clinical outcomes were assessed at a follow-up of 1 year.

**RESULTS** PAD pts using RAS blocker had suffered from more diabetes mellitus (DM, 58.9% vs. 41.1%;  $p=0.004$ ), coronary artery disease (CAD, 62.1% vs. 47.6%;  $p=0.001$ ), treated with percutaneous coronary intervention (PCI, 31.4% vs. 23.2%;  $p=0.036$ ), myocardial infarction (MI, 8.7% vs. 3.2%,  $p=0.008$ ), and the use of beta blocker (40.8% vs. 14.8%;  $p<0.001$ ) and statin (86.7%, vs. 80.4%,  $p=0.049$ ). The incidence of claudication and resting pain as the initial diagnosis for PAD were similar between the two groups. At 8 months follow-up, the incidence of primary patency were higher in PAD pts using RAS blocker (54.8% vs. 37.8%;  $p=0.027$ ). At 1-year follow up, the incidence of repeat PTA, amputation rate, and major adverse cardiovascular events (MACE) were similar between the two groups.

**CONCLUSION** In this study, although PTA pts using RAS blocker had more traditional cardiovascular risks, the incidence of restenosis, amputation rate, and MACE at 1 years were similar between the two groups. Therefore, the use of RAS blocker may be useful to improve clinical outcomes in significant PAD pts underwent PTA.

#### CRT-300.11

##### Comparison of Hypertensive and Normotensive Patients Undergoing Endovascular Revascularization for Peripheral Arterial Disease

Ji Young Park,<sup>1</sup> Seung-Woon Rha,<sup>2</sup> Byoung Geol Choi,<sup>3</sup> Se Yeon Choi,<sup>1</sup> Ji Yeon Hong,<sup>4</sup> Sang Ho Park<sup>5</sup>

<sup>1</sup>Eulji General Hospital, Seoul, Korea, Republic of; <sup>2</sup>Korea University Guro Hosp, Seoul, Korea, Republic of; <sup>3</sup>Korea University Guro Hospital, Seoul, Korea, Republic of; <sup>4</sup>KEPCO medical center, Seoul, Korea, Republic of; <sup>5</sup>Soonchunhyang University Cheonan Hospital, Cheonan, Korea, Republic of

**BACKGROUND** Peripheral arterial disease (PAD) is known to be associated with poor outcomes due to higher incidence of combined cardiovascular morbidity and mortality. We evaluated the clinical outcomes of hypertensive versus normotensive patients (pts) with PAD who underwent peripheral transluminal angioplasty (PTA).

**METHODS** The outcomes of 559 consecutive pts with symptomatic PAD who underwent PTA were enrolled for analysis. Pts were divided into two groups; PAD with hypertension (N=390) and PAD without hypertension (N=169). The incidence of restenosis, amputation rates and clinical outcomes were assessed at a follow-up of 1 year.

**RESULTS** Hypertensive PAD pts had suffered from more diabetes mellitus (DM, 78.2% vs 64.5%;  $P=0.001$ ), chronic kidney disease (CKD, 34.9% vs 13.0%;  $P<0.001$ ), and need for dialysis (23.8% vs 8.9%;  $P<0.001$ ). However, the incidence of wounds and claudication as the initial diagnosis for PAD were similar between the two groups. At 8 months follow-up, the incidence of binary restenosis, total occlusion of the limb were similar between the two groups. At 1-year follow up, the incidence of repeat PTA, amputation rate, and major adverse cardiovascular events (MACE) were similar between the two groups.

**CONCLUSION** Although hypertensive PAD pts had higher comorbidity including DM and CKD, the incidence of restenosis and amputation rate, and MACE at 1 years following successful PTA were similar with those of PAD pts without hypertension.