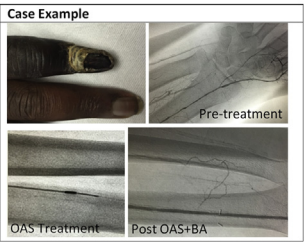
Figure

Demographics, Outcomes, Wound Status	
Avg Age	54 (n=12)
Male	83% (10/12)
African American	63% (5/8)
End Stage Renal Disease	90% (9/10)
Finger Wound	83% (10/12)
Radial Lesion Treated	82% (11/12)
Avg Balloon Inflation Pressure	5.7 atm (n=6)
Angiographic Success	100% (12/12)
Freedom From Revascularization at 30days	100% (12/12)
Healed Wound—status known	100% (4/4)
Wound status unknown	58% (7/12)

Case Example



CRT-300.03

The Use of CHA2DS2-VASc Score to Predict Risk of Stroke in General Population Without Atrial Fibrillation

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BACKGROUND CHA2DS2VASc score is used clinically for ischemic stroke risk stratification in atrial fibrillation (AF). Some studies of patients with MI and HF have shown that the CHA2DS2VASc score can be used to stratify the risk of stroke in the absence of AF. Anticoagulation may be indicated in patients with high CHA2DS2VASc score in the absence of AF.

METHOD AND RESULTS We included 1395 participants with AF who were matched to 4060 participants without AF based on age, race, and CHA2DS2-VASc score (mean age, 62 years; 57% women; 22% blacks). Participants with prevalent ischemic stroke (IS) or anticoagulant use at baseline were excluded. AF was ascertained from hospitalization discharge codes and study ECGSs. IS was physician-adjudicated. We computed (a) C-statistic to determine model discrimination of the CHA2DS2-VASc score, and (b) incidence rate difference (AF vs. no AF) for ischemic stroke. After a median follow-up of 14.7 years, 288 (5.3%) participants developed IS. The C-statistic of the CHA2DS2-VASc score for IS was not significantly different in participants with vs. without AF. The incidence rate difference of IS increases with increasing CHA2DS2-VASc score in participants with vs. without AF (Table, p for interaction between AF and CHA2DS2-VASc score <0.0001).

CONCLUSION Absolute risk of stroke in community dwellers without AF is low even with high CHA2DS2VASc score. Therefore, this population should not receive anticoagulation therapy. AF or AF-related factor, and not only vascular risk factors, drive the risk of stroke.

Stroke incidence in participants with and without AF based on CHA_2DS_2-VASc score

	CHA_2DS_2-VASc score				
	0	1	2	3	4+
No Atrial Fibrillation	345	1040	1278	793	274
# of stroke	1	13	27	25	11
Person-years	2341	6170	7251	4867	1739
Crude incidence rate (95% CI)[a]	0.43 (0.04-2.0)	2.1 (1.2-3.5)	3.7 (2.5-5.3)	5.1 (3.4-7.5)	6.3 (3.4-11.0)
Atrial Fibrillation	95	338	453	326	135
# of stroke	6	16	55	51	29
Person-years	500	1453	1660	1248	402
Crude incidence rate (95% CI)[a]	12.0 (5.0-24.7)	11.0 (6.6-17.5)	33.1 (25.2-42.8)	40.9 (30.8-53.3)	72.1 (49.3-102.1)
IRR (95% CI)	28.1 (3.4-233.3)	5.2 (2.5-10.9)	8.9 (5.6-14.1)	8.0 (4.9-12.8)	11.4 (5.7-22.8)
IRD (95% CI)	11.6 (1.9-21.2)	8.9 (3.4-14.4)	29.4 (20.5-38.3)	35.7 (24.3-47.1)	65.8 (39.3-92.3)

Abbreviations: AF, atrial fibrillation; CI, confidence interval. [a]Per 1000 person-years of follow-up. IRD, incidence rate difference; IRR, incidence rate ratio.

CRT-300.04

Does An Endovascular Procedure Improve the Quality of Life in Patients With Multiple Sclerosis

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BACKGROUND A vascular role in the etiology of multiple sclerosis (MS) has long been discussed. The extracranial stenoses of the jugular (IJV) and azygous (AZY) veins affect the venous drainage as chronic cerebrospinal venous insufficiency (CCSVI). The correlation between MS and CCSVI endeavour to elucidate the role of CCSVI and its influence on the symptoms and the signs of MS.

The primary endpoint of our open-label study was to evaluate quality of life (QoL) of MS patients with CCSVI after the endovascular procedures.

METHODS MS patients were diagnosed by revised McDonald criteria and CCSVI was evaluated by Doppler sonography if 2 or more out of 5 criteria were observed. In patients with suspecting CCSVI the catheter venography was performed. To assess the efficacy of the vascular procedures on QoL, Fatigue Severity Scale (FSS), Modified Fatigue Impact Scale (MFIS), validated Overactive bladder self-administered questionnaire (OAB-V8 Pfizer) and Multiple Sclerosis Impact Scale (MSIS-29) were used. FSS, MFIS,OAB-V8 and MSIS-29 were evaluated at baseline, 3, 6, and 12 months after vascular angioplasty.

RESULTS In our study 94 consecutive MS patients were included (22 patients with relapsing-remitting, 44 with secondary and 26 with primary progressive course of MS). In two patients (2.1%) venography did not reveal any vascular abnormality. The left IJV was more often affected. The number of venous lesions increases with the degree of disability ($p < 0.02$). FSS ($p < 0.001$) and MFIS scores - total score, as well as scores of the three subscales - physical, cognitive and psychosocial significantly improved from baseline values estimated before vascular procedures ($p < 0.05$). The improvement of the both scales correlated with the degree of pyramidal involvement ($p < 0.001$). The important improvement of the bladder function using OAB-V8 was demonstrated ($p < 0.01$). The improvement of QoL assessed by MSIS-29 questionnaire was observed ($p < 0.01$). The positive trend of all 4 parameters was maintained at one year.

CONCLUSION The amelioration of cerebral venous drainage reduce bladder disfunction, the perception of fatigue and increase mental health. Endovascular procedures in MS patients are beneficial and importantly contribute to the improvement of disability and quality of life in MS patients.

CRT-300.05

Team Based Approach for the Treatment of Arterial Wounds Reduces Amputation Rates in Critical Limb Ischemia Patients

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BACKGROUND The number of amputations performed annually in the U.S. is estimated to be 160,000 to 180,000 and more than 50% of these patients never undergo an arterial evaluation prior to amputation. The objective here is to show that a multi-disciplinary team of wound care and endovascular specialists can decrease/prevent amputations.

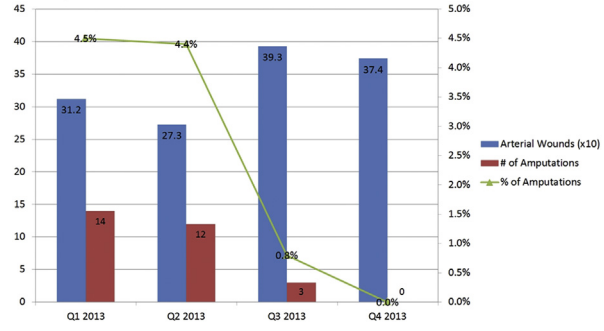
METHODS A retrospective, observational, single center (TriStar Southern Hills Advanced Wound Care Center, Nashville, TN), analysis of CLI patients with arterial wounds was completed from May, 2012 to November, 2015 to determine the impact of a team based approach on arterial wound healing and amputation rates.

RESULTS The addition of a vascular surgeon (with endovascular skills and knowledge of orbital atherectomy) to a wound care team resulted in a decrease in amputations while the number of arterial wounds under care increased (Figure 1). In addition, the percent of arterial wounds healed at 16 weeks improved from 46% to 91% during 2012-2015. In 2012, the heal rates for arterial ulcers was 54% and the time to heal in these patients was 51 days. In 2015, 91% of

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.

Figure 1. Team based approach lead to improved wound healing and reduced incidence of amputations.



CRT-300.06

Efficacy and Histomorphologic Evaluation of a Novel Large Bore Vascular Closure Device in Swine

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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 histomorpholoigcal analysis.

RESULTS All nine VCD deployments achieved patent hemostasis on first attempt as assessed by gross inspection and angiography. Serial histomorpholoigcal 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.

Serial histomorpholoigcal analysis of the VCD reveals complete absense of implant collagen (*) and neointimal endotheliazation of the prosthetic anchor by Day 90. Minimal thrombosis and neointimal or advential fibrosis was noted at all timepoints. Scale bar: 2 mm.

CRT-300.07

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

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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

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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