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TCT-1
Risk Factors for Cerebral Embolization after Carotid Artery Stenting with Embolic Protection – A DW-MRI Study in 827 Patients
Klanddia Bijnik1, Andreas Wandler2, Thilo Tuerbel3, Joachim Schofer4
1Medical Care Center, Hamburg, Germany, 2Medical Care Center Prof Mathey, Prof Schofer, Hamburg, Germany, 3Medical Care Center Prof Mathey, Prof Schofer, Hamburg, Germany, 4Medicare center Prof Mathey, Prof Schofer, Hamburg University Cardiovascular Center, Hamburg, Germany

Background: Carotidendarterectomy and CAS appear to have similar overall perioperative stroke rates, which, however, may differ in specific patient subgroups. Knowledge of the risk factors for cerebral embolic events during CAS may impact treatment decisions for the individual patient, but have not been extensively studied. Aim of the study was to evaluate the risk factors for cerebral embolization after carotid artery stenting with embolic protection.

Methods: Out of 837 consecutive patients undergoing CAS with cerebral embolic protection pre- and post-procedural diffusion weighted magnetic resonance imaging (DW-MRI) was performed for evaluation of new cerebral ischemic lesions in 728 patients (86.9%). Multivariate logistic regression analyses were performed to identify factors predictive for embolic events.

Results: New ischemic lesions were found in 32.8 % of the patients. Age, hypertension, lesion length, lesion eccentricity, and aortic arch type III were significantly associated with new ischemic lesions. Calculated lesions were negatively associated. In 25% of patients with cerebral embolic events lesions were also found in the contralateral hemisphere. Predictive factors for contralateral lesions were age, > 50% stenosis of the contralateral internal carotid artery, and an aortic arch type II with a trend for aortic arch type III.

Conclusions: Age, hypertension, lesion morphology, and aortic arch type were predictive for procedural related cerebral embolic events during embolic protected CAS. Age, significant contralateral carotid stenosis and complex aortic arch type were predictive for contralateral ischemic events. These findings may help to find the optimal treatment decision for the individual patient with carotid artery stenosis.

TCT-2
Peri-procedural Outcomes After Carotid Artery Stenting with the First 15,000 Patients Enrolled in the SAPPHIRE Worldwide Study
D. Christopher Metzger1, Robert Hibiard2, Majdi Ashchi3, Basesh Shah3, Richard Smalling4, Donald Heck6
1Wellmont CVA Heart Institute, Kingsport, USA, 2Bryan LGH Heart Institute, Lincoln, NE, 3First Coast Cardiovascular Institute, Jacksonville, FL, 4Vascular and Transplant Specialists P.C., Norfolk, VA, 5University of Texas Medical School - Houston, Houston, TX, 6Forsyth Medical Center, Salem, NC

Background: Further study is needed to determine which patient characteristics and lesion criteria derive the greatest benefit from carotid artery stenting (CAS). SAPPHIRE Worldwide is a large scale multicenter post-approval study to evaluate CAS with distal embolic protection using the Cordis PRECISE® Nitinol Stent and ANGIOGUARD™ XPR/XPR Emboli Capture Guiderewire.

Methods: Patients were enrolled with either symptomatic stenosis ≥50% or asymptomatic stenosis ≥80% and considered at high risk for surgery. Inclusion criteria included adherence to current FDA-approved labeling with these devices. The primary endpoint of major adverse events (MAE) at 30 days included any death, myocardial infarction or thrombolysis in myocardial infarction (TIMI) 3 vessel coronary revascularization. We also assessed the effect of the device on cerebral and myocardial outcomes.

Results: Enrollment began October, 2006 and is ongoing. Data were previously reported on 10,008 patients, of whom 2,963 (30%) were symptomatic and 7,045 (70%) were asymptomatic. Overall, the MAE rate at 30 days was 4.5% (death 1.3%, MI 0.6%, stroke 3.3%). There was a significant increase in the combined rate of stroke or death at 30 days between symptomatic and asymptomatic patients (6.2% vs. 3.8%, p<0.0001), and patients 75 years of age and older compared to younger patients (9.9% vs. 3.3%, p<0.0001). The 30-day stroke or death rate did not differ significantly among operator experience or volume of centers. To date, 15,000 patients have been enrolled and completed 30-day follow-up. Final data will be available and presented on the 15,000 patients at time of presentation.

Conclusions: These data compare favorably to other reports of CAS in a high-surgical risk population and are similar to results recently reported in the CREST trial comparing CAS to surgery in a non-high surgical risk population.

TCT-3
Early results of multicenter, prospective trial of TEVAR for blunt thoracic aortic injury (RESCUE Trial)
Ali Khoynezhad1, Ali Azizzadeh2, Carlos Donayre3, Alan Matsumoto4, Rod White1
1 Cedars-Sinai Medical Center, Los Angeles, CA, 2 University of Texas at Houston, Houston, TX, 3 Harbor-UCLA Medical Center, Torrance, CA, 4 University of Virginia Charlottesville, Charlottesville, VA

Background: Outcome of patients with blunt aortic injury undergoing endovascular repair is poorly understood. The aim of this study is to evaluate the early outcome of patients undergoing TEVAR for traumatic aortic injuries.

Methods: A prospective, non-randomized, multicenter trial using Medtronic Valiant Aortic Captivia was conducted at 20 sites. 50 patients with blunt aortic injury were enrolled between April 2010 and January 2012. The primary endpoint was 30-day all-cause mortality. Secondary endpoints were 30-day adverse events related to the procedure, device or aortic-related mortality and successful device delivery/deployment.

Results: 38/50 (76%) were male with mean age of 40.7 ± 17.4 years. 52 stent grafts were implanted within a median of 1.0 day following injury (mean 1.8 ± 4.0 days), 70% (35/50) of aortic injuries were grade 3 or higher. Mean injury severity score was 37.6 ± 14.3. 38/50 (74%) of stent grafts were <28 mm. The left subclavian artery was completely covered in 40% of patients (20/50) and partially covered in 18% of patients (9/50). One patient with partial coverage underwent subclavian artery revascularization. Cerebral spinal fluid was drained in 2 patients. The median procedure time was 90.5 minutes, and median hospital stay was 11 days. There was 100% successful device delivery/deployment.

Conclusions: Based on the early outcomes, TEVAR using the Valiant Captivia appears to be a promising treatment modality for blunt thoracic aortic injuries.