

Carotid, Neurovascular, and Endovascular Intervention

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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

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Background: Carotidarterectomy 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 827 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, calcified lesions were negatively associated. In 25% of patients with 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 SAPHIRE Worldwide Study

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

Methods: Patients were enrolled with either symptomatic stenosis \geq 50% or asymptomatic stenosis \geq 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 stroke.

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 (5.9% 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)

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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 blunt aortic injuries.

Methods: A prospective, non-randomized, multicenter trial using Medtronic Valiant 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 aorta, 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 . 38/52 (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.

TCT-4

Impact of Catheter Fragmentation followed by Local Intrapulmonary Thrombolysis in Acute High risk Pulmonary Embolism as Primary Therapy: Acute and Long term outcomes

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Background: Massive Pulmonary embolism (PE) requires prompt reperfusion to prevent progressive hemodynamic decline and death. We report our single center experience on immediate and long-term outcomes in high risk PE patients treated with mechanical fragmentation followed by intrapulmonary thrombolysis as a primary therapy.

Methods: 50 consecutive high risk PE patients defined as shock index (heart rate /systolic blood pressure) > 1 , $> 50\%$ pulmonary arterial obstruction and pulmonary hypertension (mean pulmonary arterial pressures (PAP) > 25 mm Hg) underwent emergent mechanical reperfusion by standard pigtail catheter; followed by intrapulmonary infusion of urokinase over 24 hours. After discharge, transthoracic echocardiography (TTE) was done at 3, 6 and 12 months.

Results: Mechanical thrombectomy restored antegrade flow in all patients. The average heart rate, mean PAP, Miller score, Shock index decreased significantly from 125 ± 18 bpm, 41 ± 8 mmHg, 20 ± 5 , 1.32 ± 0.3 to 93 ± 13 bpm, 24 ± 7 mmHg, 5 ± 2 , 0.79 ± 0.2 respectively after 24 hrs ($P < 0.0001$). A significant increase was observed in mean blood pressure and O2 saturation (78 ± 12 mm Hg vs. 92 ± 11 mm Hg, $90\% \pm 7\%$ vs. $98\% \pm 2\%$ respectively $p < 0.0001$). In-hospital mortality was 4% (2/50 pts) and major bleeding complications (local hematoma requiring blood transfusion) were seen in 2 patients. Sequential TTE based estimation of pulmonary arterial systolic pressure showed a statistically significant linear trend of reduction from 62 ± 11 mm Hg at presentation to 23 ± 6 mm Hg at 12 months.

Conclusions: Our results show that mechanical fragmentation followed by intrapulmonary thrombolysis can be offered as a primary therapy for high risk PE patients in experienced centers, similar to approach with coronary revascularization.

TCT-5

Efficacy of Cardiatris Multilayer Flow Modulator in Peripheral and Visceral Aneurysms Repair: Italian Multicenter Registry Results at One Year Follow Up

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Background: to show results of Cardiatris Multilayer Stent (CMPS) in peripheral (PAA) and visceral aneurysms (VAA) repair with/without collateral branches after one year FU.

Methods: between May 2009 and June 2010, 54 patients with PAA (35) and VAA (19) were treated with CMPS. Early (30 days), 6 months and 12 months results were analysed in terms of aneurysm thrombosis, stent and side branches patency, and shrinkage. All data were recorded in the Italian Registry of Cardiatris Procedures.

Results: intraoperative immediate technical success was achieved in all the cases. Clinical success was evaluated with CT-angiography. Complete aneurysm thrombosis rate at 1, 6, and 12 month FU was 86.5% (45/52 patients), 94.2% (49/52 patients), and 93.3% (42/45 patients) respectively. Side branches patency rate was 98.1 (51/52) at 1 and 6 months, and 97.8% (44/45) at 12 months, with a stent patency rate of 94.2% (49/52) at 1 and 6 months, and 91.1% (41/45) at 12 months. We could analyse shrinkage at each