Carotid and Neurovascular Intervention
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TCT-501
PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY AND STENTING OF EXTRACRANIAL VERTEBRAL ARTERY STENOSIS
Isabelle P Henry, Amira Benjelloun, Michel C. Henry
1Polyclinique Bois Bernard, BOIS BERNARD, France, 2Clinique Coeur et Vaisseaux, BORAT, Morocco, 3Cabinet de cardiologie, nancy, France

Background: To evaluate the safety and efficiency of vertebral angioplasty and stenting (VAS) in symptomatic patients.

Methods: 102 angioplasties in 96 pts (M:72) mean age 68.3 ± 6.7 years (22-84) left 58. All pts had multivascular diseases: carotid (CA):63, subclavian (SA): 26, coronary:64. Atheromatous lesions: 100, inflammatory: 2. Mean lesion length: 9.6 +/- 2.8 mm. Mean % stenosis 83.2 ± 7.7, mean arterial diameter: -4.8 ± 0.6 mm (4-6). 94 lesions at VO segment (ostium), 6 at V1 and 2 at V2 segments. Indications for angioplasty: dizziness (96), bilateral weakness (11), visual changes (11), diplia (10), drop attacks (20), TIA (13), ataxia (5). A protection device (filter) used in 10 pts. 20 SA angioplasties performed at the same time of VAS, 8 CA. All angioplasties performed by femoral approach. 4 by brachial approaches after failure of femoral approach. (2 successes).

Results: Technical success 100/102 (98%). 6 lesions treated by angioplasty alone: 3 VO (first 3 pts, 2 V1, 1 V2 lesion). 1 pt (inflammatory disease) treated by cutting balloon alone: 93 lesions treated with stents (direct stenting: 78). Peripheral balloon expandable stents (n=23), self expandable stents (n=4 for 3 V1 and one V2 lesions). 70 coronary stents (14 DES). 1 pt developed a TIA during the procedure. No neurological complications at 30 days Clinical success 94/96 (98%) Post-procedure arterial diameter: 4.55 ± 0.8 mm (4-6). Mean residual stenosis 2.2 ± 3.5 %. In 10 pts treated with protection devices, visible debris removed in 7 (5 Filterwire, 2 Fibremet) with the same amount of debris as during Carotid Stenting) 7 pts (8%) developed a symptomatic restenosis during the follow-up (mean: 31.4 ±28.9 months), 3 after PTA alone, 4 after PTA and stent (1 occlusion treated medically, 6 stenoses successfully treated with PTA). No restenosis after DES implantation at 1 year.

Conclusions: VAS can be performed safely and effectively with a high technical success rate, a low complication rate, a low restenosis rate and a durable clinical success in patients with symptomatic VA stenosis. Stents seem to improve immediate and long-term results. The role of protection devices and D.E.S has to be discussed.

TCT-502
Carotid Stenting Versus Endarterectomy: 10 Year Randomized Trial
Rick R. McClure, William Brooks, Michael R. Jones
1University of KY, Lexington, KY, 2Central Baptist Hospital, Lexington, KY, 3Central Baptist Hospital, Lexington, KY

Background: Modern clinical trials with short-term follow-up indicate CAS and CEAs are equivalent in reducing the risk for ipsilateral ischemic stroke secondary to carotid stenosis. A paucity of data exists regarding long term outcomes.

Methods: Patients with symptomatic and asymptomatic of all surgical risks with all patients treated with CEA (p = 0.05)).

Results: Long-term follow up was achieved in 173 patients (91%). Eighty-seven (50.2%) died within this period, most commonly of non-vascular causes. No differences in occurrence and/or risk of stroke ipsilateral to the treated artery was noted among treatment groups (p=0.61). Restenosis determined by sequential ultrasound was seen only in the CAS group (3.3%) and remained asymptomatic. The combined risk of fatal or non-fatal heart attack was highest in individuals with symptomatic compared to asymptomatic stenosis. (25.7% vs. 11.0%; p<0.005) and was higher in all patients treated with CEA (p=0.012).

Conclusions: Long-term protection against ipsilateral stroke provided by CAS and CEA is equivalent. The 10 year risk of fatal/non-fatal myocardial infarction is highest in all patients harboring symptomatic carotid stenosis at enrollment however the risks of fatal/non-fatal heart attack are much more prevalent in all patients, symptomatic and asymptomatic, randomized to CEA.

TCT-503
The Challenge of Left Internal Carotid Stenosis Stenting and Bovine Aortic Arch (BAAC)/Systematic Right Radial or Brachial Approach in 60 Consecutive Patients
piero montorsi, Stefano Galli, Paolo M. Ravagnani, Daniela Trabattoni, Giovanni Ballerini, Franco Fabbiocchi, Alessandro Lualdi, Daniele Andreini, Gianluca Pontone, Antonio L. Bartorelli
Dep’t Clinical Sciences and Community Health, University of Milan, Centro Cardiologico Monzino, IRCCS, Milan, Italy

Background: BAAC refers either to left common carotid artery (LCCA) origin from the innominate artery (type 2) or from a common origin from the aorta (type 1). When left internal carotid artery (LICA) stenosis is present, CAS from the femoral approach may be difficult, increasing the risk of technical failure and cerebral embolization.

Methods: Between 2007 and 2012, 60/505 (11.8%) consecutive pts with LICA stenosis and BAAC underwent CAS with cerebral protection from right radial or brachial approach. Type of cerebral protection (distal vs. proximal), stent (open vs. closed cell design) and technique (direct stenting vs. predilatation) were left at operator’s discretion. Double antiplatelet treatment was maintained up to 3 months after CAS. PROCEDURAL variables such as fluorooscopy time, radiation exposure, contrast medium and technical failure were compared to that of a comparable group of 13 pts with BAAC undergoing CAS by femoral catheterization.

Results: Type 2 BAAC was present in 86% of pts. The mean age was 73.9 years (75 years, 45%). Male gender was 73%, 75% had high-surgical-risk characteristics and 83% were asymptomatic. Radial or brachial approach was used in 54% and 46% of pts, respectively. Technical success was 98.3% (1 pt cross over to femoral approach). Clinical success was 96.7% (1 renal embolism and 1 minor stroke). Proximal protection (8FMO,MA) was used in 15 cases (11 brachial,4 radial) with 1 device failure (shift to filter) and 100% procedural and 100% clinical successes. Vascular complications occurred in 20 pts in the brachial/radial group, respectively. No major bleeding occurred. Fluoroscopy time (<0.05) contrast medium (<0.05), radiation exposure (p=0.08) and technical failure (1.6% vs. 16.6%, p=0.06) were reduced as compared to femoral catheterization.

Conclusions: CAS through right radial or brachial approach is safe and effective in pts with LICA stenosis and BAAC. Advantages over femoral approach include: avoidance of aortic arch, favorable anatomic pathway for LCCA cannulation, choice between two arterial accesses, use of proximal protection, low bleeding and vascular complication rates (especially from the radial approach) and early patients’ ambulation.

TCT-504
Randomized comparison of transradial and transfemoral approach for carotid artery stenting
Zosan Ruzca, Balazs Nemec, Laszlo Pinter, Balazs Berta, Karoly Toth, Sandor Nardai, Bela Merkely
1Semmelweis University, Cardiac and Vascular Center, Budapest, Hungary, 2Augusta Hospital, Vascular Surgery, Düsseldorf, Germany, 3Semmelweis University, Cardiac and Vascular Center, Budapest, Budapest, 4Bics-Kiskun County Hospital, Invasive Cardiology, Kecskemét, Hungary

Background: Limited data exist on radial access in carotid artery stenting (CAS). This multicenter prospective randomized study was performed to compare the outcome and complication rate of transradial (TR) and transfemoral (TF) CAS.

Methods: The clinical and angiographic data of 260 consecutive patients high risk for carotid endarterectomy (CEA) treated by CAS with cerebral protection between 2010 and 2012 were evaluated. Patients were randomized to TR (n=130) or TF (n=130) groups and several parameters were evaluated: Primary endpoint: MACCE, rate of access site complications. Secondary endpoint: angiographic outcome of the CAS, fluoroscopy time and X Ray dose, procedural time, cross over rate to another puncture site and hospitalisation in days.

Results: Procedural success was achieved in 260 patients (100%), the cross over rate was 10 % in the TR and 1.5% in the TF group (p<0.05). Major access site complication was encountered in 1 patient (0.9%) in the TR and in 1 patient (0.8%) in the TF group (p=ns). The incidence of MACCE was 0.9% in the TR and 0.8% in the TF group (p=ns). Procedure time (1744±742 vs. 1665±744 sec, p=ns) and fluoroscopy time (613±289 vs. 579±285 sec, p=ns) was not significantly different, but the radiation dose was significantly higher in the TR group (223±138 vs. 182±106Gy/cm², p<0.05).

Conclusions: The transradial approach for carotid artery stenting has the same efficacy and safety as transfemoral, however the cross over rate and radiation dose is higher and hospitalisation is shorter with transradial access.
Impact of coronary artery disease presence on the long-term follow-up of carotid artery stenting

Salez Arif1, Stanislaw Bartus1, Artur Dzierwiec1, Tomasz Rakowski1, Michał Brzeziński1, Michał Chyrych1, Dariusz Dudek1

1University Hospital, Krakow, Poland

Background: Carotid artery stenting (CAS) has become an alternative for carotid endarterectomy in the treatment of carotid arteries atherosclerosis due to low procedural injury and comparable procedural risk. Patients with coronary artery disease have a higher risk of surgical treatment than in CAS procedure. The impact of coronary artery disease (CAD) during long term follow-up (FU) needs reconsidering due to the intensification of aggressive pharmacotherapy in CAD during recent years.

Methods: Data of 130 symptomatic and asymptomatic patients undergoing CAS from January 2002 to December 2010 were divided in two groups: with and without CAD. All CAS procedures were performed with application of cerebral protection devices. Major adverse cerebral and cerebrovascular events (MACCE) during follow-up were defined as combination of death (cardiac and non-cardiac), myocardial infarction and stroke/TIA. Long-term outcomes of patients were stratified based on history of CAD.

Results: The mean age of patients was 66.6±9 years, majority of patients were male (80.2%). Long-term follow-up data were available in 86.2% of patients. During mean follow-up of 71.9±31.7 months all-cause mortality rate was 19.6%. The rates of myocardial infarction, stroke/TIA, and MACCE were 14.3%, 11.6%, and 37.5%, respectively. The frequency of MACCE during long-term follow-up was higher in patients with CAD vs without CAD (40.8% vs 6.7%, p = 0.01) and the mortality rate in the two groups was (22.2% vs 0%, p = 0.07) respectively.

Conclusions: Patients with symptomatic or asymptomatic carotid stenosis are a high-risk individuals with many coexisting diseases. The presence of CAD increases the risk of MACCE in such patients during long-term follow-up.

TCT-506

Predictors Of Carotid Clamping Intolerance During Carotid Artery Stenting With Proximal Embolic Protection Device. Results From An Italian Registry.

Giuseppe Giugliano1, Eugenio Stablile1, Anna Sannino2, Linda Brevetti3, Armando Pucciarelli3, Grigore Popusoi3, Tullio Tesorio4, Angelo Cioppa5, Salech Arif1, Stanislaw Bartus1, Artur Dzierwiec1, Tomasz Rakowski1, Michał Brzeziński1, Michał Chyrych1, Dariusz Dudek1

1University Hospital, Krakow, Poland

Background: Current guidelines recommend to perform Carotid Artery Stenting (CAS) procedures with embolic protection devices (EPDs). Among these, proximal EPDs such as the endovascular clamping (MO.MA, Medtronic INC) have the advantage of providing embolic protection during all phases of the intervention. However, endovascular clamping of the common carotid artery can expose the ipsilateral hemisphere to hyperperfusion and produce transient neurological symptoms (clamping intolerance). The aim of the present study was to identify the predictors of developing carotid clamping intolerance during CAS with MO.MA.

Methods: From March 2010 to March 2012, 605 consecutive patients underwent CAS using MO.MA. as EPD at our institution. Clamping intolerance was defined as any transient neurological deficit observed during occlusion time, but showing a complete recovery within 20 min after restoring antegrade flow. To identify predictors of clamping intolerance a logistic regression model was developed including all patients’ clinical characteristics, the presence of ICA stenosis > 90%, the presence of ipsilateral ECA stenosis, the presence of contralateral ICA stenosis (75-99%) and occlusion, clamping pressure ≤ 40 mmHg, and arterial pressure delta > 50 mmHg.

Results: 184 patients (30.4%) developed clamping intolerance during the CAS procedure. Compared to patients without clamping intolerance, those who experienced intolerance showed a lower clamping pressure (42.3±12.7 vs 61.9± 5.4 mmHg, p < 0.001). ROC curve analysis showed that clamping pressure was the most consistent predictor with a c-statistic of 0.85 (95% CI 0.82-0.88) and best cut-off being ≤ 40 mmHg (sensitivity 68.5%, specificity 93.3%). Logistic regression analysis showed that the most powerful independent predictor of clamping intolerance was a clamping pressure ≤ 40 mmHg (HR=3.42, 95% CI 19.7-59.6) and that the most powerful clinical predictor of such clamping pressure was the presence of contralateral ICA occlusion (HR=3.1, 95% CI 10.6-2).

Conclusions: Clamping intolerance may occur in up to a third of the patients undergoing CAS with endovascular clamping. This event is more common in those patients presenting a clamping pressure ≤ 40 mmHg.

TCT-507

Racial/Ethnic Variation in Carotid Artery Revascularization Utilization and Outcomes: Analysis from the NCDR®

Siddharth A. Wayangankar1, Herbert Aronow1, Douglas E. Drachman1, Kevin F. Kennedy1, Faisal Latif1, Bhavin C. Patel1, Chittur A. Sivaram1, Alfonso Tafur2

1University of Oklahoma Health Sciences Center, Edmond, OK, 2St. Joseph Mercy Hospital, Ann Arbor, MI, 3Massachusetts General Hospital, N/A, 4Mid America Heart and Vascular Institute, St. Luke’s Hospital, Kansas City, MO

Background: It is not known whether racial or ethnic disparities observed with other revascularization procedures are also seen with carotid artery stenting (CAS) and endarterectomy (CEA).

Methods: We compared the utilization of CAS and CEA across racial/ethnic groups within the CARE Registry® between May 2005 - Dec 2012. Differences in clinical characteristics, procedural variables, and major adverse cardiac and cerebrovascular events (MACCE) were studied.

Results: Between 2005 and 2012, of the 13,129 patients who underwent CAS, majority were non-Hispanic Caucasians (NHC 89.3%), followed by African Americans (AA 4.4%), Hispanics (H 4.3%), and other groups (OG 2.0%). A similar distribution was observed among the 10,953 patients undergoing CEA (NHC 92.6%, AA 3.5%, H 2.8%, and OG 1.1%). During this time period, a trend toward proportionate increase in CAS utilization was observed in NHC and OG whereas the opposite was observed among H and AA (Fig 1). This trend persisted even when hospitals performing both CAS and CEA were exclusively analyzed. Adherence to anti-platelet and statin therapy was significantly lower among AA post-CAS. In-hospital MACCE remained comparable across groups post-CAS whereas post-CEA, there was a significant decline in MACCE among NHC only (p=0.04). At 30 days, the incidence of death (2.2%), stroke (7.2%), and MACCE (8.8%) was higher among AA post-CEA (p<0.05).

TCT-508

Table I. Demographic and clinical data

<table>
<thead>
<tr>
<th>Demographic and clinical data of all study patients</th>
<th>Radial group (n=130)</th>
<th>Femoral group (n=130)</th>
<th>P value</th>
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<tr>
<td>Age</td>
<td>66.8±8.9</td>
<td>66.7±10.2</td>
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<tr>
<td>Male (%)</td>
<td>60.8</td>
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<td>Hypertension (%)</td>
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<td>Hyperlipidaemia (%)</td>
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<td>Diabetes mellitus (%)</td>
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<td>36.9</td>
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<td>Obesity (%)</td>
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<td>Smoker (%)</td>
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<td>Peripheral artery disease (%)</td>
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<td>Coronary artery disease (%)</td>
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<td>Positive family history (%)</td>
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<tr>
<td>Dialysis (%)</td>
<td>6.2</td>
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