Randomized Comparison of Flow Reversal vs Distal Filter for Cerebral Protection During Carotid Artery Stenting in Patients With Stable Carotid Disease

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Background: previous studies revealed high incidence (up to 80%) of new asymptomatic cerebral lesions after CAS, with concomitant proximal protection with filter. Heterogeneity in patient selection, CAS techniques and operators experience could have biased previous results. We sought to establish if proximal protection with flow reversal, performed by experienced operators in a high volume center, may be more effective than filters in preventing cerebral embolization during CAS in patients with stable carotid disease.

Methods: patients undergoing CAS with cerebral embolic protection for internal carotid artery stenosis were randomly assigned to flow reversal (FR) or filter protection (FP). The primary endpoint was the incidence of new cerebral ischemic lesions assessed by diffusion-weighted magnetic resonance imaging (MRI). Secondary endpoints were: the number and diameter of new ischemic lesions; the number of microembolic signals (MES) assessed by bilateral transcranial Doppler monitoring during the all phases of the procedure. Major cardiovascular and cerebral events (MACCE) at 30 days were recorded. Expected rate of new cerebral lesion was 50% in FP, 17% in FR (as reported in previous studies); with alfa 5% and 1-beta 80%, sample size was 60 patients. Results: 60 consecutive patients (mean age 72±6.8) were randomized. Compared with FP (n=30), FR (n=30) did not reduce the incidence, the number and the diameter of new cerebral ischemic lesions (table). Lesions in the contralateral hemisphere were found in 3.3% and 0% of patients. Overall MES were not significantly reduced by FR compared to FP (table). The 30 day MACCE rate was 3.3% and 3.3% for FP versus FR (p NS).

Conclusions: in this randomized trial of patients with stable severe carotid disease undergoing CAS, incidence of new ischemic lesions was very low in both groups. FR protection did not significantly reduce cerebral embolization.

TCT-552

Particulates from Hydrophilic Coated Guiding Sheaths Embolize to the Brain

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Background: Peripheral vascular interventions frequently employ guiding sheaths with surface modifications (i.e., hydrophilic coatings) raising the concern for embolization. Methods: A self-expanding stent and delivery system (SDS) were deployed in the iliac and/or carotid arteries of 23 Yucatan miniosines. Access was via the femoral or carotid arteries. SDS were deployed through a Cook® Flexor Angi Guiding Sheath with a hydrophilic coating (AQ® hydrophilic coating). In one non-stented control animal the guiding sheath was advanced but no SDS was deployed. Animals were euthanized at 30, 90 & 180 days after intervention and brains were removed for histological analysis. In addition, coating material from the surface of a non-deployed guiding sheath was obtained and examined microscopically.

Results: The Cook guiding sheath was associated with intravascular accumulation of an amorphous, non-refractile, non-crystalline, and non-birefringent embolic foreign material in sections of porcine brain which, on H&E staining, appeared lightly basophilic and slightly stippled. Material was observed at all time points and in all major regions of the brain, involving 52% of all test animals, and in the non-stented control animal. The incidence of embolic material was higher (63%) with carotid stenting which was limited to a single incidence of focally extensive chronic infarction in one brain. In vitro incubation of the Cook guiding sheath was associated with progressive separation and sloughing of its hydrophilic coating. Microscopic assessment of the sloughed hydrophilic coating was interpreted to be morphologically consistent with the emboli observed in the brains of animals exposed to the Cook guiding sheath. Conclusions: The Hydrophilic Coating of Cook® Flexor Angi Guiding Sheaths sloughed and embolized to the brain during deployment in a porcine model, especially following carotid access. Further monitoring and documentation of potential side-effects of embolized material in clinical scenarios is warranted.

TCT-553

Abstract Withdrawn

TCT-554

Evaluation of flow reversal during carotid artery stenting as the first choice for embolic protection - no contraindications!

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Background: To assess the use of proximal protection devices in consecutive patients as the preferred means of cerebral embolic protection for primary stenting of carotid stenosis.

Methods: This was a prospective single-center study to evaluate the technical and clinical success of proximal protection devices as the first choice for embolic protection in symptomatic (≥50%) and asymptomatic (≥70%) carotid stenosis. Proximal protection devices were used for embolic protection in 124 consecutive patients. No patients had been excluded for anatomical reasons. The Gore Flow Reversal Device (W.L.Gore, Flagstaff, AZ) was used in 92 patients, the Mo.Ma Ultra device in 32 (Medtronic, Minneapolis, MN) patients. We have used the Mo.Ma Ultra so that we were able to establish a flow reversal with this system, too. Follow-up duration was 30 days.

Results: Mean age was 71 ± 8 years. Seventy-five percent of patients were male (n=93). Twenty-six of 124 (21%) treated stenoses were symptomatic. Technical success was achieved in 122 of 124 cases (98%). Due to the anatomical conditions, in 2 patients, flow reversal could not be established. In both cases, additional distal filter devices were used. Carotid stenting was successful in 124 lesions (100%). Ten patients (8.1%) had classic contraindications to flow reversal (3 high-grade ostial stenoses of the external carotid artery, 7 contralateral occlusions of the internal carotid artery) in none of whom any complications occurred. There were no procedural neurological events. Within 30 days of follow-up, one patient had an ischemic stroke on day 11.

Conclusions: Proximal protection using flow reversal is a safe method as the first choice of embolic protection. It can be used with a high rate of technical success.

TCT-555

CAROTID ANGIOPLASTY AND STENTING IN OCTOGENARIANS. IS IT SAFE AS SURGERY. NEW DATA

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Background: Recent studies, registries (EXACT, CAPTURE… randomized studies (CREST) have shown that carotid angioplasty stenting (CAS) is at higher risk than surgery (CEA) in elderly patients. The aim of this study was to evaluate if CAS performed in octogenarians is as safe as surgery with better indications, choice of the devices, experienced operators.

Methods: 1104 patients (male 794) mean age 70.8± 9.7 years underwent 1164 CAS for de novo lesions (n=1022) restenoses (n=57) post radiation arteritis (n=12) post trauma aneurysms (n=2). Indications for treatment: symptomatic carotid stenosis > 70 % (63%) or asymptomatic stenosis > 80 %. Patients were separated in 2 age groups: < 80 y (174 patients, 177 CAS) and < 80 y (930 patients, 987 CAS). 188 CAS performed without protection (N.P.) 6 in patients > 80 y, 976 with protection (NP+) (occlusion balloon: 334, filters: 637, reversal flow: 6) 171 in patients >80y. Data analysis included neurological complications, death and myocardial infarction (MI) rate at 30 days, anatomical particularities. Technical points will be described depending on the age of the patient on day 11.

Results: -Technical success < 80 years: 985/987 > 80 years: 176/177
-Technical success < 80 years: 985/987 > 80 years: 176/177
-30 day outcomes

<table>
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<th>1164 PROCEDURES</th>
<th>TOTAL</th>
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<td>15 (1.5%)</td>
<td>7 (3.8%)</td>
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EPD: EMBOLIC PROTECTION DEVICES

TCT Abstracts/Carotid Intervention
Conclusions: CAS can be performed in elderly patients without higher risk than in younger patients. But good indications, a meticulous technique, protection devices are mandatory and some technical points must be pointed out to avoid neurological complications and failures.

TCT-556
Optical Coherence Tomography in Carotid Artery Stenting: Feasibility and Safety
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Background: Optical coherence tomography (OCT) is an optical signal acquisition and processing method that captures micrometer-resolution, three-dimensional images from within optical scattering media that has a higher homaxial resolution than intravascular ultrasound. Currently, characterization of carotid atherosclerotic disease is based on the anatomic degree of stenosis; however, imaging technologies such as OCT can be a useful adjunct to provide additional information in characterizing carotid atherosclerotic disease and guiding therapeutic interventions without increasing peri-procedural morbidity or mortality.

Methods: We evaluated 60 consecutive patients (35 men; mean age 75 ± 4 years) undergoing protected carotid artery stenting (CAS) since OCT was available in our lab (November 2011). 27 of these 60 patients underwent CAS utilizing OCT evaluation and the remainder underwent CAS without OCT guidance. Our purpose is twofold: (1) to present the first published US experience (and largest experience globally) utilizing OCT to guide CAS from a safety and feasibility standpoint and to demonstrate that OCT does not increase procedure time or perioperative morbidity or mortality; and (2) to highlight 3 substantive cases to explain challenges in image acquisition, image interpretation, and using images to guide interventional strategy.

Results: No procedural or in-hospital neurological complications occurred in either group (stroke/death 0%). The total amounts of contrast and fluoroscopic time/dose did not vary significantly between those patients undergoing OCT-guided CAS or CAS without OCT guidance. OCT images revealed innovative features such as rupture of the fibrous cap plaque prolapse, large lipid pool, and stent malposition in a high percentage of patients; these findings were then used to guide intraoperative decision-making.

Conclusions: Intravascular OCT during CAS appears to be feasible and safe. We have established a protocol to successfully, consistently and safely obtain images that may subsequently be used to guide interventional decision-making with the ultimate aim of improving short and long-term outcomes.

TCT-557
Carotid Artery Stenting with Double Cerebral Embolic Protection in Symptomatic Patients
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Background: Previous trials comparing carotid artery stenting (CAS) with carotid endarterectomy (CEA) demonstrated controversial results, mainly in symptomatic patients, because of higher stroke rate. However, the increase of the experience of the operators, the improvement of the stents and of the embolic protection devices (EPD) has made CAS a highly competitive procedure. In this study we tried to assess the feasibility and the safety of using double EPD (proximal and distal) in high-risk patients.

Methods: We collected data about all consecutive patients with symptomatic or asymptomatic carotid artery stenosis who underwent CAS and analyzed clinical and procedural characteristics as well as immediate and 30-day outcomes. All the procedures were performed after discussion of the cases and after reviewing imaging examination results with neurologists. Neurologic visits and duplex scans were scheduled 24 hours and 1 month after the procedure.

Results: Between November 2007 to March 2014 277 underwent CAS. In 26 of them (9.4%) double EPD was used (distal filter + MoMa, Medronic, Minneapolis, MN). The whole population was at high cardiovascular risk: 51.9% of the patients had known coronary artery disease, 5.8% congestive heart failure, 41.9% aged ≥75 years. Many patients (48.7%) had a complex plaque (soft, ulcerated, with thrombus). The stent implanted were closed-cell in 64.6%, hybrid in 23.5% and open cell in 11.9%. In comparison with the patients treated with single EPD, those with double EPD presented with a higher rate of complex plaque (100% vs 43.4%, p < 0.0001). There was no difference between the 2 groups in primary success (100% vs 96.4%, p=0.16) and in the rate of major complications at 30 days: death (0% vs 0.7%, p=0.45), major stroke (0% vs 0.8%, p=0.45), and minor stroke (0% vs 1.2%, p=0.66).

Conclusions: In our experience, in symptomatic patients with high-risk lesions, the use of double EPD (proximal and distal) is safe and effective in minimizing the risk of cerebral embolization.

TCT-558
Abstract Withdrawn

TCT-559
The Link Between S100β And Audio-Verbal Memory Performance In Patients After Carotid Revascularization
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Background: S-100β has shown to be a sensitive marker of clinical and subclinical cerebral damage, such as stroke and mild traumatic brain injury. In this study we try to reveal the link between S100B and postoperative cognitive impairment in patients undergoing carotid revascularization by using the audio-verbal learning test (AVLT). The AVLT has shown to be a sensitive measure for cognitive changes following carotid revascularization.

Methods: Blood samples were taken in 31 patients undergoing carotid revascularization (15 carotid endarterectomy, 6 carotid stenting (CAS) with filter protection device, and 10 CAS with flow reversal) pre-operatively, peri-operatively, and 2, 6, and 24 hours postoperatively. The serum S100β was measured using S100 Cobas®. All patients were cognitively tested one month postoperatively.

Results: For S100β, repeated measures show significant within subjects differences (ANOVA F=19.64, p<0.001 (see Figure 1)). Because the two hours postoperative S100β resulted in the highest peak value, this measure was used to correlate to AVLT measures. There was no relation between the sum of the five encoding trials (r=0.172, p=ns.), but the long-term recall showed a non-significant trend (r=-0.338, p=0.078). Higher S100β values are associated with lower long-term audio-verbal memory scores.

Conclusions: In this study S100β follows the typical increase early postoperatively, as shown in other studies. The magnitude of this increase seems marginally correlated to memory performance one month postoperatively. S100β may therefore have a predictive value for longer lasting cognitive impairments.

TCT-560
Transradial and Transbrachial Arterial Approach for Simultaneous Carotid Angiographic Examination and Stenting Using Catheter Looping and Retrograde Engagement Technique
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Background: The purpose of this study was to introduce a novel and safe technique with high procedural success for carotid artery stenting (CAS).

Methods: From April 2004 to May 2009, 161 patients underwent CAS using either a high transradial arterial approach (TRA, defined as 10 cm above styloid process) or a trans-brachial arterial approach (TBA) with a 7F arterial sheath. Selective carotid angiography was performed using a 6F Kimny guiding catheter and Teflon wire (260 cm in length) by Catheter Looping And Retrograde Engagement Technique (CLARET) with the guiding catheter seated on the right coronary cusp and its tip engaged into the common carotid artery (CCA). Teflon wire was introduced into the CCA again after the diagnostic procedure, followed by replacement of the 6F Kimny guiding catheter by a 7F Kimny catheter for CAS using one of the following techniques: (1) direct-engagement method, i.e., from right innominate artery into the right CCA; (2) looping method plus double-wire technique (utilized two Teflon wires to provide an adequate support) for both the right and left CCA; and (3) looping method plus a PercuSurge balloon anchoring at the external carotid artery. 

Results: This distinctive technique offered 100% diagnostic success and 99.4% CAS success. Two patients (1.2%) experienced major ischemic stroke after CAS and two (1.2%) died during hospitalization.

Conclusions: The results of the present study showed that high TRA/TBA using CLARET for CAS in patients with severe carotid artery stenosis is safe and technically feasible with an extremely high success rate.