TCT-551

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 ischemic lesions after CAS, with conflicting results comparing 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 macroembolic 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 alpha 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.

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Particulates from Hydrophilic Coated Guiding Sheaths Embolize to the Brain

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Background: Peripheral vascular interventions frequently employ guiding sheaths with a hydrophilic coating. SDS were deployed through a Cook Flexor Ansel Guiding Sheath. Patients were randomized to embolization with a hydrophilic coated sheath (group 1, n=33) or an uncoated sheath (group 2, n=33). After embolization, the hydrophilic coating of Cook was limited to a single incidence of focally extensive chronic infarction in one patient. 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 Ansel 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.

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Abstract Withdrawn

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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 performed at 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.

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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 percutaneous transcatheter angioplasty (PTA) or stenting (CAS) is more effective than surgery (CEA) in elderly patients.

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 (n=15) inflammatory arthritis (n=12) post trauma aneurysms (n=2). Indications for treatment: symptomatic carotid stenosis > 70 % (63%) or asymptomatic stenosis > 80 % (37%). Patients were separated into 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 >80 y. 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

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EPD: EMBOLIC PROTECTION DEVICES

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