

affected by ulceration. Despite the existence of numerous studies favouring angiosome-targeted revascularization the concept remains controversial. The aim of our study was to compare the main treatment strategies in CLI with tissue lesion, surgical and endovascular revascularization, using angiosome concept in terms of the wound healing and freedom from major amputation.

**Methods:** The study cohort comprises a total of 975 consecutive patients who underwent endovascular or surgical revascularization in below the knee arteries between January 2010–July 2013. Data collection was performed by reviewing patient's records from our prospectively collected database as well as patient's angiograms and MRIs. Statistical analysis was performed using a SPSS statistical software (SPSS v. 22.0, SPSS Inc., Chicago, Ill., USA). Differences between bypass surgery and PTA groups were adjusted by estimating a propensity score, which was employed for one-to-one matching as well as adjust for other variables in estimating their impact on the postoperative outcome.

**Results:** Propensity score matching with a calliper width of 0.02 resulted in 252 pairs with similar baseline and operative characteristics. Actuarial analysis showed the positive impact of angiosome targeted bypass surgery on wound healing ( $p = 0.046$ , HR 1.295, 95%CI 1.005–1.668) compared with angiosome targeted angioplasty. Interestingly also non-angiosome targeted bypass surgery achieved better wound healing rates than PTA independently of the angiosome oriented strategy ( $p = 0.001$ , HR 1.890, 95%CI 1.292–2.766). Cox proportional hazards analysis showed that angiosome targeted revascularization ( $p = 0.036$ , HR 1.294, 95%CI 1.017–1.647), bypass surgery ( $p < 0.0001$ , HR 1.791, 95%CI 1.412–2.272), C-reactive protein  $\leq 10$  mg/dL ( $p = 0.005$ , HR 1.416, 95%CI 1.110–1.806) and the number of affected angiosomes ( $p = 0.024$ , HR 0.854, 95%CI 0.744–0.979) were independent predictors of wound healing (Fig. 1). The non-angiosome targeted angioplasty was associated with the highest risk of major amputation as compared with non-angiosome targeted bypass surgery ( $p = 0.049$ , HR 0.569, 95%CI 0.325–0.997), angiosome targeted bypass surgery ( $p = 0.033$ , HR 0.589, 95%CI 0.362–0.958) and angiosome targeted angioplasty ( $p = 0.005$ , HR 0.556, 95%CI 0.371–0.834).

**Conclusion:** The healing of ulcer in patients with CLI is significantly better in bypass surgery independent of the angiosome concept rather than angiosome-targeted percutaneous transluminal angioplasty. Furthermore low C-reactive protein and low number of affected angiosomes plays important role in both wound healing and the risk for major amputation.

### A New Carotid 3D MRI Sequence for Stenosis Measurement and Plaque Characterization at the Same Time

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**Introduction:** Risk of stroke related to carotid atherosclerosis depends on degree of stenosis and carotid plaque vulnerability. We propose a new 3D MRI sequence (3D-T1) allowing measurement of these parameters at the same time without gadolinium injection.

**Methods:** Forty-six patients with atherosclerotic plaque of carotid bifurcation underwent the new 3D-T1 sequence (4 minutes acquisition time), and the standard protocol comprising Gadolinium-enhanced MR Angiography (CE-MRA) for stenosis measurement and 2D HR-MRI sequences for plaque characterization on a 3T MRI scanner. Qualitative evaluation was performed by

two observers on both the 3D-T1 and the whole standard protocol with the following parameters: overall image quality and plaque components evaluation (intraplaque hemorrhage IPH, lipid core, calcifications, ulceration and fibrous cap rupture). Furthermore, the NASCET degree of stenosis was calculated on 3D-T1 and CE-MRA. Comparison between 3D-T1 and the standard protocol were performed using Mann–Whitney  $U$  tests and Pearson coefficients of correlation. Inter-observer agreements were assessed by Kappa. Among these patients, 18 underwent carotid endarterectomy. Histological examination was performed. Sensitivity and specificity of the 2 protocols for diagnosis of vulnerable plaque features were calculated. Correlation between histological and MRI results were assessed using Spearman's rank correlation test.

**Results:** Four patients were excluded due to artifacts on the standard protocol and one on the 3D-T1. 3D-T1 showed a better image quality in comparison with the standard protocol ( $3.59 \pm 1.02$  vs.  $3.27 \pm 1.01$ ;  $p < 0.05$ ). For the stenosis degree, correlation between 3D-T1 and CE-MRA was excellent ( $R = 0.93$ ) despite a trend for T1-3D to overestimate it (8.9%; IC:  $-11.95$  to  $29.82$ ). Interobserver variability showed a good agreement between observers ( $\kappa > 0.87$ ). Sensibility and specificity for IPH diagnosis was 50% and 100% for the standard protocol and 100% and 83% for the 3D-T1 sequence. Sensibility and specificity were similar between 3D and 2D sequences for diagnosis of the others plaque features. Histological correlation was better with 3D-T1 than with standard protocol for IPH (0.87 vs. 0.57) (Fig.). There was no difference for lipid core and calcification (0.66 and 0.88). For ulceration and cap rupture, correlation was slightly better with the standard protocol (0.86 vs. 0.72).

**Conclusion:** The 3D-T1 sequence without gadolinium injection allows a reproducible measure of carotid stenosis in comparison of CE-MRA with a slight overestimation. The 3D-T1 sequence also allows a reliable and faster carotid atherosclerotic plaque characterization, in comparison with the reference protocol with an improvement of IPH diagnosis.

### Urgent Carotid Artery Stenting Does Not Increase the Risk for Peri-procedural Complications – A Nationwide Population-based Registry Study

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**Introduction:** Current ESVS guidelines recommend that patients with a significant symptomatic stenosis should be operated within 14 days of onset of symptoms. However, recent reports indicate that carotid endarterectomy (CEA) within 2 days after a neurologic event may be associated with a higher peri-procedural risk of stroke. If urgent carotid artery stenting (CAS) carries a similar high risk is unclear.

The aim of this study was to analyse whether urgent CAS after a neurologic event increases the peri-procedural risks.

**Methods:** Retrospective analysis of all CAS registered in a validated nationwide registry between January 1st, 2005 and June 7th, 2013. Only symptomatic patients treated with CAS for a stenosis of the internal carotid artery were included. The rates of stroke and acute myocardial infarctions (AMI) were recorded at 30 days. Mortality data were collected from the national death registry.

Patients were categorized according to time from index event until surgery; 0–2 days, 3–7 days, 8–14 days, and 15–180 days. A secondary analysis was performed for 0–7 days, 8–14 days,

15–28 days and 29–180 days. Primary outcome was 30-days combined stroke and death rate.

**Results:** In total 269 patients had complete data and were included in the analysis. The demographic and clinical data were similar in the groups. The 30-day combined stroke and death rate did not differ significantly between the groups; 0% (0/12) in the group treated 0–2 days, versus 3.9% (3/76), 2.9% (2/68), and 5.3% (6/113) for the patients treated at 3–7 days, 8–14 days and 15–180 days respectively ( $p = 0.759$ ). The 30-day stroke and death rate in the secondary analysis were also similar between groups; 3.4% (3/88), 2.9% (2/68), 6.3% (3/48), and 4.6% (3/65) respectively, ( $p = 0.813$ ).

**Conclusion:** In this national registry study, limited by small numbers, patients that underwent urgent CAS after onset of a neurologic event had no additional risk of suffering from a perioperative complication.

### Lessons from 500 Adverse Event Reports on SFA Stents from MAUDE Database—need for Action by ESVS?

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**Introduction:** When a Boeing aircraft develops a problem at New York, within the next 24 hrs the whole Boeing fleet, the world over, gets an alert with initial defect report, cause and a fix. On the other hand when the trigger mechanism of delivery system of an SFA stent fails in a London Hospital, nothing similar happens. FDA mandates the manufacturers to report all adverse events within 30 days on the MAUDE database. An analysis of 500 adverse event reports on SFA stents reveals lessons for the vascular societies and calls for unified action for the sake of patient safety.

**Methods:** MAUDE database was searched for all adverse event reports on SFA stents from 01/04/2012 to 31/03/2014. Each report lists the event description, the date, patient injury, intervention if required and the manufacturer's narrative.

**Results:** 500 SFA stent adverse reports were recorded and analysed. All known manufacturers were listed. Adverse reports from 2 stent manufacturers were significantly more than the others. A similar deployment failure was reported for over 1 year by one manufacturer. More than 1/3rd of the reported cases had either a failure in deployment of the stent or retrieval of the standard delivery system (sds). In another 1/3rd the stent was damaged after deployment—twisted, torqued, fractured, or occluded. In the remaining 1/3rd there were multitudes of problems from breakage of sds components and their retention within the patient to dislodgment.

Adverse patient effects included Acute Limb ischemia, limb loss and death. Majority required endovascular intervention, failing which an open procedure was performed in 20% of patients.

Analysis of manufacturer's narrative rarely revealed no attributable cause, the malfunction, mal-deployment was labeled as procedure related and not device related. The manufacturer's narrative often stated that the device met pre-release specifications and no manufacturing defect could be identified.

**Conclusion:** A review of adverse event reports from manufacturer's clearly indicates that the adverse event was procedure related and probably due to the operator not exercising due care or not following the IFU. There is a need for the societies to take a lead in user adverse event reporting, analysis and communicating these to the centre's on a definitive time scale in a more open and unified manner to prevent patient harm and improve outcomes.

### Impact of Early Pelvic and Lower Limbs Reperfusion and Aggressive Perioperative Management on Spinal Cord Ischemia During Thoracoabdominal Aortic Aneurysm Endovascular Repair

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**Introduction:** Spinal cord ischemia (SCI) is a devastating complication following thoracoabdominal aortic aneurysm (TAAA) endovascular repair. In an attempt to reduce its occurrence, we have modified our implantation protocol in January 2010 by withdrawing all large sheaths from the iliac arteries as soon as possible during the procedure. In addition, we have also modified our perioperative protocol (aggressive blood and platelet transfusion, median arterial pressure monitoring >80 mmHg, and systematic cerebrospinal fluid drainage except for type 4 TAAA).

**Methods:** Between October 2004 and December 2013, we have performed 204 TAAA endovascular repairs with custom made devices manufactured with branches and fenestrations to perfuse the visceral vessels. Data from all patients were prospectively collected in an electronic database. We compared the early outcomes of patients treated before (group 1, 43 patients) and after (group 2, 161 patients) modification of our implantation and perioperative protocols.

**Results:** Group 1 and 2 patients had similar comorbidities (median age at repair 70.9 years [65.2–77]), aneurysm characteristics (median diameter 58.5 mm [53–65]), and length of procedure (median 190 min [150–240]). The in-hospital mortality rate was 11.6% in group 1 vs. 5.6% in group 2 respectively (RR = 0.481 [0.17–1.36];  $p = 0.09$ ). The spinal cord ischemia rate was 14% vs. 1.2% (RR = 1.148 [1.016–1.296];  $p = 0.001$ ) respectively. If we exclude Type 4 TAAA from this analysis, the spinal cord ischemia rate was 25% (6/24 patients) in group 1 vs. 2.1% (2/95 patients) in group 2 (RR = 1.306 [1.034–1.648];  $p < 0.001$ ) respectively.

**Conclusion:** Early restoration of arterial flow to the pelvis and lower limbs and aggressive perioperative management significantly reduces SCI following TAAA endovascular repair. With this modified approach, extensive TAAA endovascular repairs are associated with low rates of SCI.

### Endovascular Management of Rupture in Acute Type B Aortic Dissections

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**Introduction:** Reports of thoracic endovascular aortic repair (TEVAR) for complicated acute type B dissection bring together a large range of clinical presentations. With a 50% of 30-day mortality rate when managed with open surgery, rupture is the most dramatic complication of acute type B dissections. We investigated the outcomes of TEVAR for acute type B dissection complicated by rupture (R-ABD) to assess the results of this particularly critical subgroup.

**Methods:** A review of consecutive TEVAR for R-ABD in two tertiary centers was performed using prospectively maintained database.

**Results:** Between 2000 and 2014, 24 patients (mean age 68 years; 14 males) underwent TEVAR for R-ABD. Sixteen (67%) were in shock (Systolic blood pressure <80 mmHg) before surgery and 20 required chest drainage for hemothorax. Proximal entry tear was in zone 2 in 7 (29%) and 3 in 17 (71%). Five patients required coverage of the left subclavian artery for adequate proximal