

operatively with suturing of the graft proximally due to poor proximal seal without endoleaks.

Conclusion: Acute bEVAR of ruptured TAAA provides good results in the short-term suggesting it as a valid option in the acute setting.

Analysis of 100 Reported Deaths after Elective TEVAR/EVAR in 1 Year Reveals At Least Half were Preventable!

R. Gambhir, H. Slim, H. Mistry, A. Choong, D. Valenti, H. Rashid

King's College Hospital, London, United Kingdom

Introduction:

Objective: To analyse the cause of deaths following elective TEVAR and EVAR as reported on manufactures and user facility device experience (MAUDE) database of US FDA and identify areas of concern.

Methods: The MAUDE database was searched for deaths associated with the use of Aortic stent grafts. The search criteria used was 'System, Endovascular Graft, and Aortic Aneurysm'. Search was done retrospectively from 31 Jan 2015 for 100 consecutive death reports.

Results: Six different Aortic stent graft systems had been used. There was no report of device related death, all were procedure related with non IFU use in over 20% of cases. 30% deaths occurred in peri-operative period from causes like hypovolemia from aortic or iliac rupture, retrograde or antegrade dissections, air embolism. Difficulty in deployment of stents or accessories was reported in 15% and acute renal failure causing death in 25%. Open conversion was associated with death in over 90% of patients. Delayed rupture with or without sac expansion was noted in 20% of patients. No cause of death was identified in 10% of patients.

Conclusion: Deaths after elective TEVAR/EVAR are a reality that cannot be ignored. There is a need to take ownership of the reporting systems by physicians. Better sharing of adverse events may help prevent some of these deaths.

Intra-operative Analysis of Motor Evoked Potentials to Evaluate the Risk of Paraplegia during Branched EVAR for Thoraco-abdominal Aneurysm

P.M. Kasprzak, M. Wagenschwanz, B. Cucuruz, W. Mess, R. Kopp

Department of Vascular and Endovascular Surgery, University Hospital Regensburg, Germany

Introduction: Spinal cord ischemia (SCI) is a major complication after aortic repair of thoraco-abdominal aneurysms (TAAA). Recently, we introduced the concept of temporary aneurysm sack perfusion (TASP) to prevent paraplegia during branched EVAR for TAAA. These patients seem to have a reduced risk for post-operative SCI, but they need a second procedure for branch occlusion. Intra-operative assessment of the neurologic status using motor evoked potentials (MEPs) might allow an intra-operative decision for TASP and early or late side branch completion.

Methods: From 07/2007–01/2015, 105 patients with TAAA were treated with branched standard or custom made endovascular stent grafts. All patients received peri-operative spinal drainage. Temporary aneurysm sack perfusion (TASP) was performed for SCI prevention in n = 52 patients. Intra-operative assessment of spinal cord function using MEPs was performed in n = 27 (26%) patients. In n = 20 (19%) patients additional intra-operative balloon occlusion of the TASP branch was performed. Demographic data, comorbidities, neurologic symptoms and variables related to aneurysm or endovascular treatment were analyzed. Post-operative SCI was defined as motor deficiency (Tarlov 0–2) day 0–7 post-operatively and day 30.

Results: Post-operative transitory neurologic deficiency was observed in 21/105 (20%) patients and 13/105 (12%) patients had paraplegia after 30 days. In the TASP group 3/52 (5.7 %) patients had severe SCI after bEVAR, two of them after secondary branch occlusion. None of these 2 patients had intra-operative MEPs monitoring. Based on intra-operative MEPs monitoring with an additional side branch balloon occlusion test for 45 min 7/20 patients with low risk of spinal cord ischemia had intra-operative immediate side branch occlusion and no paraplegia. In 13/20 patients a decrease of motor evoked potentials

was observed and these patients had TASP with secondary side branch occlusion.

Conclusion: Neurologic monitoring during bEVAR with MEPs is feasible and with relevant information regarding the risk of paraplegia and the therapeutic concept including TASP.

Definite Plaque Echolucency is Associated with a Higher Risk of Ipsilateral Ischaemic Stroke during Early Follow up in the Asymptomatic Carotid Surgery Trial-1 (ACST-1)

A. Huibers, G.J. de Borst, R. Bulbulia, A. Halliday on behalf of ACST-1 Collaborative Group

Nuffield Department of Surgical Sciences, University of Oxford, Oxford, United Kingdom

Introduction: Several carotid plaque characteristics, including a thin fibrous cap, lipid necrotic core and intraplaque haemorrhage, have been suggested as potential markers to select patients at high risk for future stroke. On ultrasound, these "high risk" characteristics appear echolucent. The Asymptomatic Carotid Surgery Trial-1 (ACST-1) is the largest randomised controlled trial comparing carotid endarterectomy (CEA) with deferral of CEA in patients with severe asymptomatic carotid artery stenosis. We aimed to assess whether ultrasound characterized plaque echogenicity was a predictor for ischaemic stroke in asymptomatic patients randomized to deferred treatment in ACST-1.

Methods: 814 patients randomized to deferred surgery who had baseline plaque assessment confidentially classified as echolucent (>25% soft plaque) or non-echolucent (<25% soft plaque) were studied. Kaplan-Meier survival curves were used to calculate cumulative rates of ipsilateral ischaemic stroke in both groups.

Results: Life table analysis showed a significantly higher 5 year risk of ipsilateral stroke in patients with definite echolucent plaques (8.0%; 95% CI: 6.4 - 9.6) when compared to patients with definitely non-echolucent plaques (3.1%; 2.1 - 4.1) (p = 0.009). After adjustments of other risk factors, plaque echolucency was associated with a 2.5 times increased risk of ipsilateral ischaemic stroke (HR 2.52, 95% CI: 1.20–5.25; p = 0.014). The use of lipid lowering therapy was low in both groups during the first 5 years after randomization but rose significantly thereafter and during the later stages of follow up, and was more commonly prescribed in patients with echolucent plaques (p = 0.001). The risk of ipsilateral ischaemic stroke at 10 years was similar for both levels of echogenicity (p = 0.421) as was the risk of any stroke at 10 years (p = 0.632).

Conclusion: Definite plaque echolucency (>25% soft plaque) might be a predictor of ipsilateral stroke and is associated with a higher 5 year ipsilateral stroke risk in these trial patients with asymptomatic carotid disease. The similar stroke risk outcomes at 10 years for both groups could possibly be explained by a higher use of lipid lowering therapy during later follow up in patients with definite echolucent plaques.

Validation of a Risk Scoring System to Predict Life Expectancy after CEA in Patient with Asymptomatic Carotid Artery Stenosis

I. Barbetta, D. Bissacco, M. Carmo, S. Bonardelli, S. Trimarchi, V. Catanese, P.G. Settembrini

U.O. di Chirurgia Vascolare, Ospedale S. Carlo Borromeo, Università di Milano – Cattedra di Chirurgia Vascolare, Spedali Civili di Brescia, Università di Brescia – U.O. di Chirurgia Vascolare II, IRCCS Policlinico di S. Donato, Università di Milano, Italy

Introduction: Recent guidelines regarding surgical treatment of asymptomatic carotid stenosis recommend exclusion of patients without a minimum life-expectancy of 3–5 years. Purpose of this study is to validate a previously derived risk scoring system to identify factors associated with a higher mortality during long-term follow up after carotid endarterectomy (CEA).

Methods: The factors were derived from a cohort of 648 asymptomatic patients. According to the weight of each variable, the score system included age (<70 = 0 points, 70–79 = 4 points, ≥80 = 8 points), renal status (creatinine ≥1.5 = 4 points and dialysis = 8 points), chronic

obstructive pulmonary disease (COPD), diabetes mellitus, coronary artery disease (CAD), lack of statins on treatment (1 point each). We calculated the total risk score as the sum of all risk factors' points, and grouped them into 4 categories. Another 334 asymptomatic patients were extracted from two tertiary care medical centers to derive a validation cohort (VC). The derivation cohort (DC) and VC were clinically similar in terms of age (74 vs. 72 years) and gender (males 66% vs. 63%). Among risk factors, they differed only for CAD (20% vs. 30% $P < 0.001$) and statin therapy (44% vs. 60% $P < 0.001$). They were comparable as per diabetes (29% vs. 24% $P = 0.09$), mean creatinine (1.13 vs. 1.1 mg/dL, $P = 0.58$) and COPD (13.2% vs. 10.5%, 0.21).

Results: Median follow up was 56 months for DC and 65 months for VC. Long term mortality was comparable among DC and VC: overall survival was $98.9 \pm 0.4\%$ vs. $96.7 \pm 0.1\%$ at 1 year; $92.7 \pm 1.1\%$ vs. $91 \pm 1.6\%$ at 3 years and $84.7 \pm 1.7\%$ vs. $85.2 \pm 2\%$ at 5 years. When comparing groups, 5 years survival rate was $97 \pm 1.5\%$ for patients with score 0–3, $88.4 \pm 2.2\%$ for score 4–7, $69.6 \pm 4.7\%$ for score 8–11, and $48.1 \pm 13.5\%$ for score ≥ 12 ($P < 0.0001$) in the DC (fig. 1). Similarly in the VC we found a $95.5 \pm 2\%$ 5 years survival for score 0–3, $89.5 \pm 2.7\%$ for score 4–7, $65 \pm 6.1\%$ for score 8–11 and $44.8 \pm 14.1\%$ for score ≥ 12 ($P < 0.0001$).

Conclusion: Our scoring system is a simple, 6 variables clinical tool for prediction of post-operative life expectancy. The score showed to predict adequately the long-term survival in a validation cohort from two different medical centers. Patients with a score >8 have a poor long term survival, and the advantage of CEA in this subgroup is questionable. We believe that our score may help clinicians while selecting asymptomatic patients who would benefit from CEA.

Stroke/Death Rates Following Carotid Artery Stenting and Carotid Endarterectomy in Contemporary Administrative Dataset Registries: A Systematic Review.

K.I. Paraskevas, E.L. Kalmykov, A.R. Naylor

Leicester Royal Infirmary, Leicester, United Kingdom

Introduction: Randomized trials have reported contradictory findings regarding outcomes after carotid artery stenting (CAS) versus carotid endarterectomy (CEA). Despite this, the 2011 American Heart Association (AHA) guidelines expanded CAS indications, partly because of data from the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST), but also because of improving outcomes in Industry-sponsored 'high risk for CEA' CAS Registries. The aim of the current systematic review was to see whether there was a parallel reduction in procedural risk after CAS in contemporary administrative dataset registries.

Methods: PubMed/Medline, Embase and Cochrane databases were systematically searched from January 1, 2008 until February 23, 2015 for administrative dataset registries reporting outcomes after both CEA and CAS.

Results: Twenty-one registries reported outcomes after $>1,500,000$ procedures. CAS had similar stroke/death rates with CEA in one registry involving 'average risk' asymptomatic and in two registries involving 'average risk' symptomatic patients. Stroke/death rates after CAS were significantly higher than CEA in 9/15 registries involving 'average risk' asymptomatic and in 11/18 registries involving 'average risk' symptomatic patients. In five registries, CAS was associated with higher stroke/death rates than CEA for both symptomatic and asymptomatic patients, but formal statistical comparison was not reported. CAS was associated with stroke/death rates that exceeded risk thresholds recommended by the AHA in 9/15 registries involving 'average risk' asymptomatic patients and in 13/18 registries involving 'average risk' symptomatic patients. In 5/18 registries, the procedural risk after CAS in 'average risk' symptomatic patients exceeded 10%.

Conclusion: Data from contemporary administrative dataset registries suggest that stroke/death rates following CAS remain significantly higher than after CEA and frequently exceed accepted AHA thresholds. In this systematic review, there was no evidence of a sustained decline in procedural risk after CAS. The extremely high published risks in some symptomatic registries suggest that clinical governance is not being applied.

Genetic Polymorphisms Influence in the Response to Clopidogrel in Peripheral Artery Disease Patients Following Percutaneous Transluminal Angioplasty

F. Fernández-Quesada¹, X. Díaz-Villamarín², C.L. Dávila-Fajardo², J. Sánchez-Ramos³

¹ Department of Vascular Surgery, Hospital Universitario San Cecilio, Granada, Spain

² Department of Clinical Pharmacy, Hospital Universitario San Cecilio, Granada, Spain

³ Department of Cardiology, Hospital Universitario San Cecilio, Granada, Spain

Introduction: Clopidogrel has provided significant reduction in major vascular events in patients with peripheral artery disease (PAD), particularly among those following PTA. Clopidogrel antiplatelet effects differ according to genotype ABCB1 and CYP2C19, establishing normal, intermediate and poor metabolizers; and good or bad carriers. Intermediate and poor metabolizers (CYP2C19 *1/*2,*2/*2) and bad transporters (ABCB1TT) are responsible for the poor antiplatelet drug response. These polymorphisms have been associated with differences in clopidogrel response in acute coronary syndrome patients but effects in peripheral artery disease are still understudied.

To determine the onset of ischemic vascular events requiring reoperation of the affected limb or amputation in patients undergoing PTA (+/- stent) during one year after treatment and to study the association with the presence of genetic polymorphisms CYP2C19 and ABCB1 (separately and combined) a case-control study was performed.

Methods: 72 patients with PAD of the lower limbs under PTA (+/- stent) and treated with clopidogrel were selected. CYP2C19*2 (rs4244285), CYP2C19*3 (rs4986893) and ABCB1 (rs1045642) polymorphisms were genotyped using Taqman allelic discrimination technique to compare post-operative results.

Results: Out of the 72 patients included in the study, 18 were CYP2C19*2 allele carriers, no patient carried CYP2C19*3 allele and 14 patients were ABCB1TT genotype. Out of the 72 patients, 25 (34.7%) had an event during follow up (1 year). Patients with at least some loss of function had a higher rate of events compared to patients with no loss of function allele (OR = 5.0, 95% CI 1.75–14.27, $p = 0.003$), and patients with some loss of function allele were associated with a worse Fontaine evolution (OR = 13.96, 95% CI 4.44–43.82, $p < 0.0001$). Reduced and non metabolizer patients also had a higher rate of events compared to good metabolizer patients (OR = 4.49, 95% CI 1.25–13.84, $p = 0.009$) and a worse outcome Fontaine grade (OR = 8.31, 95% CI 2.36–29.16; $p = 0.001$). However, poor transporter patients didn't show a statistically significant higher rate of events comparing to good transporters although they showed a worse Fontaine grade evolution (OR = 4.75, 95% CI 1.32–17.07, $p = 0.017$).

Conclusion: Poor metabolizer patients of clopidogrel have a higher risk of major ischemic events and worst Fontaine grade evolution. Our results support the role of CYP2C19 and ABCB1 polymorphisms as genetic markers for vascular events in patients with peripheral vascular disease of the lower limbs undergoing PTA and treated with clopidogrel.

Polymeric Microspheres as Novel Delivery Platform for Pro-angiogenic Therapy

Z. Aref, H.A.B. Peters, M.R. de Vries, J. Zupancich, A.Y. Nossent, P.H.A. Quax

Leiden University Medical Center, Leiden, The Netherlands

Introduction: Angiogenesis, the sprouting of new capillaries from the microvasculature, improves blood perfusion of ischemic tissue. Various pro-angiogenic factors have the potential to stimulate and enhance angiogenesis. However, due to poor drug delivery and rapid clearance, clinical trials on pro-angiogenic therapeutics in peripheral arterial disease have only been marginally successful. We aimed to develop a polymer-based drug delivery platform enabling local, sustained delivery of pro-angiogenic