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Agreement between site-reported and ultrasound core laboratory results for duplex ultrasound velocity measurements in the Carotid Revascularization Endarterectomy versus Stenting Trial

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Objective: Patients in the Carotid Revascularization Endarterectomy vs Stenting Trial (CREST) had duplex ultrasound (DU) scans prior to treatment and during follow-up to document the severity of carotid disease and the anatomic outcome of carotid endarterectomy (CEA) or carotid artery stenting (CAS). An ultrasound core laboratory (UCL) reviewed DU data from the clinical sites. This analysis was done to determine the agreement between site-reported and UCL-verified DU velocity measurements.

Methods: Clinical site DU worksheets, B-mode images, and Doppler velocity waveforms for the treated carotid arteries were reviewed at the UCL. The highest internal carotid artery peak systolic velocity (PSV) and associated Doppler angle were verified. If the angle was misaligned by >3 degrees, it was remeasured at the UCL and the PSV was recalculated. Agreement for PSV was defined as site-reported PSV within ±5% of UCL-verified PSV. Transcription errors were corrected by the UCL but were not considered as disagreements. Follow-up analysis was limited to patients who received the assigned treatment.

Results: The UCL reviewed 1702 prior-to-treatment and 1743 12-month follow-up DU scans (873 CEA, 870 CAS) from 111 clinical sites. Site-reported and UCL-verified PSV agreed in 1124 (66%) of the prior-to-treatment scans and 1200 (69%) of the follow-up scans. In those cases with a disagreement, Doppler angle accounted for disagreement in 339 (59%) of the prior-to-treatment scans and 277 (51%) of the follow-up scans. Based on a threshold PSV for ≥70% stenosis of ≥230 cm/s on the prior-to-treatment scans and ≥300 cm/s on the follow-up scans, UCL review resulted in reclassification of stenosis severity in 75 (4.4%) of the prior-to-treatment scans and 13 (0.75%) of the follow-up scans. There is evidence that the proportion of reclassification at follow-up was greater for CAS (10 scans; 1.2%) than for CEA (3 scans; 0.34%) (P = .057).

Conclusions: There was a high rate of agreement between site-reported and UCL-verified DU results in CREST, and UCL review was associated with a low rate of stenosis reclassification. However, angle alignment errors were quite common and prompted recalculation of velocity in 20% of prior-to-treatment scans and 18% of follow-up scans. The use of a UCL provides a uniform process for DU interpretation and can identify sources of error and suggest technical improvements for future studies.

Carotid stenting versus endarterectomy in patients undergoing reintervention after prior carotid endarterectomy

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Background: Outcomes for patients undergoing intervention for restenosis after prior ipsilateral carotid endarterectomy (CEA) in the era of carotid angioplasty and stenting (CAS) are unclear. We compared perioperative results and durability of CAS vs CEA in patients with symptomatic or asymptomatic restenosis after prior CEA and investigated the risk of reintervention compared with primary procedures.

Methods: Patients undergoing CAS and CEA for restenosis between January 2003 and March 2012 were identified within the Vascular Study Group of New England (VSGNE) database. End points included any stroke, death or myocardial infarction (MI) within 30 days, cranial nerve injury at discharge, and restenosis ≥70% at 1-year follow-up. Multivariable logistic regression was done to identify whether prior ipsilateral CEA was an independent predictor for adverse outcome.

Results: Out of 9305 CEA procedures, 212 patients (2.3%) underwent redo CEA (36% symptomatic). Of 663 CAS procedures, 220 patients (33%) underwent CAS after prior ipsilateral CEA (31% symptomatic). Demographics of patients undergoing redo CEA were comparable to patients undergoing CAS after prior CEA. Stroke/death/MI rates were statistically similar between redo CEA vs CAS after prior CEA in both asymptomatic (4.4% vs 3.3%; P = .8) and symptomatic patients (6.6% vs 5.8%; P = 1.0). No significant difference in restenosis ≥70% was identified between redo CEA and CAS after prior CEA (5.2% vs 3.0%; P = .5). Redo CEA vs primary CEA had increased stroke/death/MI rate in both symptomatic (6.6% vs 2.3%; P = .05) and asymptomatic patients 4.4% vs 1.7%; P = .03). Prior ipsilateral CEA was an independent predictor for stroke/death/MI among all patients undergoing CEA (odds ratio, 2.1; 95% confidence interval, 1.3-3.5). No difference in cranial nerve injury was identified between redo CEA and primary CEA (5.2% vs 4.7%; P = .8).

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Conclusions: In the VSGNE, CEA and CAS showed statistically equivalent outcomes in asymptomatic and symptomatic patients treated for restenosis after prior ipsilateral CEA. However, regardless of symptom status, the risk of reintervention was increased compared with patients undergoing primary CEA.

ITER Registry and results of Gore Excluder endograft for the treatment of elective infrarenal abdominal aortic aneurysms

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Background: To report the midterm results of elective endovascular aortic repair (EVAR) of abdominal aortic aneurysms (AAAs) in a multicenter, clinical unsponsored registry using the Gore Excluder endograft.

Methods: This study is a retrospective analysis of a multicenter, prospective registry that involved nine centers in Italy. Periodic clinical and radiographic follow-up with computed tomography scans were performed at 1, 6, and 12 months after the procedure, and on a yearly basis thereafter..

Results: A total of 872 patients underwent elective EVAR. Primary technical success was 97.5%, and hospital mortality was 1.0% (9/872). At least 816 (93.6%) patients underwent a follow-up control. Freedom from all-cause death was estimated to be 97.9% at 1 year, 93.4% at 3 years, and 88.5% at 5 years. Aneurysm-related mortality was 1.6% (n = 13) with only two late AAA-related deaths observed at 21 and 36 months. Significant predictors of all-cause mortality included age ($P < .001$) and AAA maximum diameter ($P = .027$). Overall conversion rate was 2.3% (n = 19). Mean elapsed time from initial intervention to surgical conversion was 23 ± 18 months (range, 0-52 months). Late rupture was detected in four (0.5%) cases: two of these patients died after conversion. The rate of any reintervention was 9.4% (n = 77); most of them were required within the first 24 months. The leading cause of reintervention was endoleak (n = 41; 5.0%). Limb thrombosis occurred in nine (1.1%) cases. Freedom from reintervention at 1, 3, and 5 years of follow-up were 98.6%, 94.6%, and 86.5%.

Conclusions: The ITalian Gore Excluder Registry is the largest clinical unsponsored registry using a single device, with the longest follow-up period so far. The present experience confirms the effectiveness of EVAR using the Gore Excluder with low rates of mortality, migration, reintervention, and limb thrombosis.

One-year outcomes from an international study of the Ovation Abdominal Stent Graft System for endovascular aneurysm repair

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Objective: This study evaluated 1-year safety and effectiveness outcomes of the United States regulatory trial for the Ovation Abdominal Stent Graft System (TriVascular Inc, Santa Rosa, Calif) for endovascular repair of abdominal aortic aneurysms (AAAs).

Methods: This prospective, multicenter, single-arm trial was conducted at 36 sites in the United States, Germany, and Chile to evaluate the safety and effectiveness of the Ovation stent graft. From November 2009 to May 2011, 161 patients (88% males; mean age, 73 ± 8 years) with AAAs (mean diameter, 54 ± 9 mm) were treated with the Ovation stent graft. The main body is a modular two-docking limb device with a 14F outer diameter delivery system, active suprarenal fixation, and polymer-filled proximal rings that accommodate the aortic neck for seal. Main inclusion criteria included proximal aortic neck length ≥7 mm, inner neck diameter between 16 and 30 mm, distal iliac landing zones length ≥10 mm, and diameter between 8 and 20 mm. Patients were treated under a common protocol, including clinical and imaging follow-up at discharge, 30 days, 6 months, and annually through 5 years. A Clinical Events Committee adjudicated adverse events, an independent imaging core laboratory analyzed imaging, and a Data Safety and Monitoring Board provided study oversight. Complete 1-year follow-up data were available for this report.

Results: The Ovation stent graft was implanted successfully in 161 patients (100%), including 69 (42.9%) by percutaneous access. General anesthesia was used in 106 patients (65.8%). Technical success was 100%, and mean procedure time was 110 minutes. Median procedural blood loss was 150 mL, and median hospital stay was 1 day. The 30-day major adverse event rate was 2.5%. At 1 year, AAA-related and all-cause mortality were 0.6% and 2.5%, respectively. Major adverse event and serious adverse event rates through 1 year were 6.2% and 38.5%, respectively. The 1-year treatment success rate was 99.3%. The imaging core laboratory reported no stent graft migration or type I, III, or IV endoleaks. At 1 year, type II endoleaks were identified in 34% of patients, and AAA enlargement was identified in one patient (0.7%). No AAA rupture or conversion to open surgery was reported. AAA-related secondary procedures were performed in 10 patients (6.2%) for 12 findings, including endoleak (six), aortic main body stenosis (three), and iliac limb stenosis or occlusion (three).

Conclusions: The 1-year results of the Ovation Abdominal Stent Graft System demonstrate excellent safety and effectiveness in treatment of patients with AAAs, particularly in patients with challenging anatomic characteristics, including short aortic necks and narrow iliac arteries. Longer-term follow-up is needed.

Utility of direct angiosome revascularization and runoff scores in predicting outcomes in patients undergoing revascularization for critical limb ischemia

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