Selected Abstracts from the September Issue of the Journal of Vascular Surgery

**Lifetime registry of endovascular aneurysm repair: Open repair surgical controls in clinical trials**

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**Purpose:** The improvement of available endovascular aortic aneurysm repair (EVAR) devices is critical for the advancement of patient care in vascular surgery. The goal of this article is to report a highly detailed, closely monitored, audited, pooled multicenter cohort of open surgical abdominal aortic aneurysm (AAA) repairs that has potential for use in future EVAR studies as a control data set.

**Methods:** Open surgical AAA repair (open) data from four investigational device exemption clinical aortic endograft trials were tested for poolability, merged, and analyzed for the intervals of 0 to 30 days and 31 to 365 days.

**Results:** The data set includes 323 open patients (83% men; mean age, 70 years). Operative mortality at 30 days was 2.8%. The mean age of women was 3 years older than men, and mortality at 30 days for women was 5.7% compared with 2.2% for men (P = .18). Operative mortality for patients with large AAAs (≥5.5 cm, 3.6%) was not different than for patients with small aneurysms (≤5.5 cm, 2.4%, P = .54). All-cause mortality at 1 year was 6.7%, with significant predictors including age, sex, and renal failure. Women had 2.6-fold greater 1-year all-cause mortality rate (13.2%) than men (5.4%, P = .04), but statistical significance was lost after correction for age. Two additional AAA-related deaths occurred between days 31 and 365, resulting in a 1-year AAA-related mortality of 3.5%.

**Conclusion:** This data set provides a tightly controlled, thoroughly detailed, and audited experience that has the potential to serve as an open control group for future EVAR trials.

**A randomized, placebo-controlled trial of doxycycline after endoluminal aneurysm repair**

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**Background:** The late durability of endovascular aneurysm repair (EVAR) has been limited by progressive aortic degeneration believed to be mediated by matrix metalloproteases (MMP). The goal of this study was to evaluate the effect of a MMP inhibitor, doxycycline, on EVAR.

**Methods:** Patients undergoing EVAR were randomized to doxycycline (100 mg twice daily) or placebo for 6 months following the procedure. Clinical data, blood samples, and computed tomography (CT) scans were obtained preoperatively, postoperatively (blood only), and at 1- and 6-month follow-up. Forty-four subjects were analyzed based on intention-to-treat.

**Results:** Plasma MMP-9 decreased significantly below baseline in the doxycycline (N = 20) treated patients at 6 months (−16.4% ± 20.7%, P < .05) while there was a nonsignificant increase in the placebo (N = 24) group (128.1% ± 73.5%). This was primarily related to changes between 1 and 6 months. In patients with endoleaks at 6 months, plasma MMP-9 increased in 83% of the placebo treated patients, but in only 14% of the doxycycline treated group (P < .03). Among endoleak-free patients with AneuRx or Excluder endografts, doxycycline treatment resulted in greater decreases in maximum aortic diameter than placebo treatment (−13.3% ± 3.3% vs −3.8% ± 3.0%, P < .05).

**Conclusion:** There is evidence of persistent MMP release representing ongoing aortic degradation after endografting which can be inhibited by doxycycline. In analyses based on the endograft used, treatment with doxycycline also demonstrated evidence of increased aortic dimensional stability, a surrogate marker for long-term success of EVAR. Although encouraging, these results require confirmation in larger patient populations. Doxycycline should undergo more thorough evaluation as a potential adjuvant treatment to improve the results of EVAR, particularly in certain subgroups.

**Pivotal results of the Medtronic Vascular Talent Thoracic Stent Graft System: The VALOR Trial**

Ronald M. Fairman, Frank Criado, Mark Farber, Christopher Kwokel, Manish Mehta, Rodney White, Anthony Lee, J. Michael Tuchek

**Objective:** Avoidance of nephrotoxic contrast agents during endovascular repair of abdominal aortic aneurysms (EVAR) may reduce the incidence of renal dysfunction following the procedure. Carbon dioxide (CO2) angiography is a safe alternative to iodinated contrast media vastly under-utilized by vascular surgeons. We herein describe our experience with a simple angiographic technique using CO2 for EVAR guidance that does not require a separate angiographic catheter.

**Methods:** Eighteen patients underwent EVAR using angiography with CO2 delivered through the endograft sheath. The renal and hypogastric arteries were localized for endograft deployment exclusively with CO2 in all patients. Completion angiography was done with CO2 in all patients and an additional angiogram with iodinated media was done in 13 cases.

**Results:** All endograft deployments were done successfully with CO2 angiography injected through the endograft delivery systems and femoral access sheaths. Additional iodinated media completion angiography did not modify the procedure in any case. All patients were discharged within two days after surgery. There were no ischemic or systemic complications related to CO2 administration. Follow-up CT-scan revealed well positioned endografts with the expected patent renal and hypogastric arteries in all patients, and no additional endoleaks. No significant deterioration in renal function occurred in any case.

**Conclusion:** Carbon dioxide angiography conducted through the endograft delivery sheath is reliable for endograft deployment, safe, non-toxic and inexpensive. In addition, it may expedite EVAR by eliminating a number of angiographic catheter placements and exchanges during the procedure. This favorable experience warrants further utilization of this technique.

**Catheter-less angiography for endovascular aortic aneurysm repair: A new application of carbon dioxide as a contrast agent**

Enrique Criado, Loay Kabbani, Kyung Cho

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Suboptimal use of statin therapy in elderly patients with atherosclerosis: A population-based study

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Background: Current evidence suggests that statin use plays an important role in improving adverse cardiovascular outcomes in patients with atherosclerosis. However, limited population-based data are available on use of statin therapy in these patients in Canada. We sought to study trends in statin use to treat these patients in Ontario during a 10-year period.

Methods: We conducted a population-based cross-sectional time series analysis between April 1, 1995, and March 31, 2004, using health care data from Ontario, Canada.

Results: During the study period, 343,154 elderly patients with atherosclerosis were identified. Of these, 235,615 (68.7%) had coronary artery diseases (CAD), 115,012 (33.5%) had cerebrovascular disease (CVD), and 23,886 (7.0%) had peripheral arterial disease (PAD). About 46% were women, and mean patient age was 77.1 (SD, 7.5) years. During the study period, the percentage of statin users was lowest among PAD and CVD patients, followed by patients with both a history of PAD and CVD.

Conclusion: The use of statin therapy in elderly patients with symptomatic atherosclerosis has increased substantially during the past decade, but many patients remain untreated. The suboptimal use is greatest among patients with PAD or CVD, or both, and lowest in patients with CAD. Given the heightened risk of cardiovascular adverse outcomes in patients with atherosclerosis, these data have important and immediate implications.

Efficacy of duplex ultrasound surveillance after infrainguinal vein bypass may be enhanced by identification of characteristics predictive of graft stenosis development

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Objective: Controversy regarding the efficacy of duplex ultrasound surveillance after infrainguinal vein bypass led to an analysis of patient and bypass graft characteristics predictive for development of graft stenosis and a decision of secondary intervention.

Methods: Retrospective analysis of a contemporary, consecutive series of 353 clinically successful infrainguinal vein bypasses performed in 329 patients for critical (n = 284, 88%) or noncritical (n = 69, 20%) limb ischemia enrolled in a surveillance program to identify and repair duplex-detected graft stenosis. Variables correlated with graft stenosis and bypass repair included: procedure indication, conduit type (saphenous vs non-saphenous vein; reversed vs non-reversed orientation), prior bypass graft failure, postoperative ankle-brachial index (ABI) < 0.85, and interpretation of the first duplex surveillance study as "normal" or "abnormal" based on peak systolic velocity (PSV) and velocity ratio (Vr) criteria.

Results: Overall, 126 (36%) of the 353 infrainguinal bypasses had 174 secondary interventions (endovascular, 100; surgery, 74) based on duplex surveillance; resulting in 3-year Kaplan-Meier primary (46%), assisted-primary (80%), and secondary (81%) patency rates. Characteristics predictive of duplex-detected stenosis leading to intervention (PSV: 443 ± 94 cm/s; Vr: 6.8 ± 6.9) were: "abnormal" initial duplex testing indicating moderate (PSV: 180–300 cm/s; Vr: 2–3.5) stenosis (P < 0.001), non-single segment saphenous vein conduit (P < 0.01), warfarin drug therapy (P < 0.01), and redo bypass grafting (P < 0.001). Procedure indication, postoperative ABI level, statin drug therapy, and vein conduit orientation were not predictive of graft revision. The natural history of 141 (40%) bypasses with an abnormal first duplex scan differed from "normal" grafts by more frequent (51% vs 24%, P < 0.001) and earlier (7 months vs 11 months) graft revision for severe stenosis and a lower 3-year assisted primary patency (68% vs 87%, P < 0.001). In 52 (15%) limbs, the bypass graft failed and 20 (6%) limbs required amputation.

Conclusions: The efficacy of duplex surveillance after infrainguinal vein bypass may be enhanced by modifying testing protocols, e.g., rigorous surveillance for "higher risk" bypasses, based on the initial duplex scan results and other characteristics (warfarin therapy, non-single segment saphenous vein conduit, redo bypass) predictive for stenosis development.

Carotid endarterectomy within 2 weeks of minor ischemic stroke: A prospective study

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Objective: Data from multicenter symptomatic trials have shown that benefit from carotid endarterectomy (CEA) was greatest in patients with carotid disease operated within 2 weeks of their last ischemic event. We prospectively analyzed the safety and benefit of CEA performed within 2 weeks of a stroke.

Methods: The study involved patients with acute minor stroke admitted to two stroke units who underwent CEA within 2 weeks of their last ischemic event, once they were considered neurologically stable. Preoperative workup included scoring ischemia-related symptoms according to a modified ranking scale (mRS), carotid duplex scan, transcranial Doppler ultrasound, and head computed tomography or magnetic resonance imaging. All patients underwent neurological assessment on admission, 1 day before and 2 days after CEA, and at discharge. A complete neurological and ultrasound follow-up was performed at 1, 6, and 12 months after CEA, then yearly. All procedures were eversion CEA under deep general anesthesia, with selective shunting. Endpoints were perioperative (30-day) stroke/mortality rate or cerebral bleeding and long-term stroke recurrence or cerebral hemorrhage.

Results: Between 2000 and 2005, 102 patients with a mRS ≤ 2 underwent CEA within a median 8 days of acute ischemic stroke. Shunting and contra-lateral carotid occlusion were found significantly correlated. There were no perioperative strokes or deaths, or cerebral hemorrhage. All patients were followed up for a mean 34 months (range 1–66) with no recurrent stroke or cerebral bleeding.

Conclusions: CEA can be performed within 2 weeks of carotid-related ischemic stroke with no perioperative stroke or cerebral bleeding, preventing the risk of stroke recurrence.

A prospective evaluation of the outcome after small saphenous varicose vein surgery with one year follow-up

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Objective: The aim was to examine the effect of various surgical maneuvers during standard surgery for small saphenous varicose veins (SSV).

At 1 month, 6 months, 1 year, and annually thereafter. These endovascular results were compared with retrospective open surgical data from three centers of excellence.

Results: The Evaluation of the Medtronic Vascular Tissue Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms (VALOR) trial enrolled 195 patients, and 189 were identified as retrospective open surgical subjects. Compared with the open surgery group, the VALOR test group had similar age and sex distributions, but had a smaller TAA size. Patients received a mean number of 2.7 ± 1.3 stent graft components. The diameters of 25% of the proximal stent graft components implanted were <26 mm or >40 mm. Left subclavian artery revascularization was performed before the initial stent graft procedure in 5.2% of patients. Iliac conduits were used in 21.1% of patients. In 33.5% of patients, the bare spring segment of the most proximally implanted device was in zones 1 or 2 of the aortic arch. In 194 patients (99.5%), vessel access and stent graft deployment were successful at the intended site. The 30-day VALOR results included perioperative mortality, 2.1%; major adverse events, 41%; incidence of paraplegia, 1.5%; paraparesis, 7.2%; and stroke, 3.6%. The 12-month VALOR results included all-cause mortality, 16.1%; aneurysm-related mortality, 3.1%; conversion to open surgery, 0.5%; target aneurysm rupture, 0.5%; stent graft migration >10 mm, 3.9%; endoleak (12.2%), stent graft patency, 100%; stable or decreasing aneurysm diameter, 91.5%; and loss of stent graft integrity, four patients. No deployment-related events or perforation of the aorta by a graft component occurred. The Thoracic Thoracic Stent Graft showed statistically superior performance with respect to acute procedural outcomes (P < 0.001), 30-day major adverse events (41% vs 84.4%, P < 0.001), perioperative mortality (2% vs 8%, P < 0.01), and 12-month aneurysm-related mortality (3.1% vs 11.6%, P < 0.002) vs open surgery.

Conclusions: The pivotal VALOR 12-month trial results demonstrate that the Medtronic Vascular Talent Thoracic Stent Graft System is a safe and effective endovascular therapy as an alternative to open surgery in patients with TAA who were considered candidates for open surgical repair.
**Methods:** This was a prospective cohort study of patients that underwent small saphenous varicose vein surgery. Two-hundred nineteen consecutive patients (234 legs) with isolated primary or recurrent small saphenous varicose veins undergoing surgery were enrolled in a multicenter study involving nine vascular centers in the United Kingdom. Operative technique was determined by individual surgeon preference; clinical and operative details, including the use of stripping, were recorded. Clinical examination (recurrence rates) and duplex imaging (superficial and deep incompetence) were evaluated at six weeks and one year after surgery.

**Results:** A total of 204 legs were reviewed at one year; 67 had small saphenous varicose vein stripping, 116 had saphenopopliteal junction (SPJ) disconnection only, and the remainder had miscellaneous procedures. The incidence of visible recurrent varicosities at one year was lower after SSV stripping (12 of 67, 18%) than after disconnection only (28 of 116, 24%), although this did not reach statistical significance. There was no significant difference in the rate of numbness at one year between those who had SSV stripping (20 of 71, 28%) and those who had disconnection only (38 of 134, 28%). The rate of SPJ incompetence detected by duplex at one year was significantly lower in patients who underwent SSV stripping (9 of 67, 13%) than in those who did not (37 of 115, 32%) ($P < .01$).

**Conclusion:** Stripping of the SSV significantly reduced the rate of SPJ incompetence after one year without increasing the rate of complications.