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Selected Abstracts from the October Issue of the Journal of Vascular Surgery☆

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Cost-effectiveness of open vs endovascular repair of abdominal aortic aneurysm: Results of a multicenter randomized trial

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Objective: This study was conducted to determine the costs and comparative cost-effectiveness of two methods of abdominal aortic aneurysm (AAA) repair in the Open Versus Endovascular Repair (OVER) Veterans Affairs (VA) Cooperative Study, a multicenter randomized trial of 881 patients.
Methods: The primary outcomes of this analysis were mean total health care cost per life-year and per quality-adjusted life-year (QALY) from randomization to 2 years after. QALYs were calculated from EuroQol (EQ)-5D questionnaires collected at baseline and annually. Health care utilization data were obtained directly from patients and from national VA and Medicare data sources. VA costs were obtained from national VA sources using methods previously developed by the VA Health Economics Resource Center. Costs for non-VA care were determined from Medicare claims data or billing data from the patient's health care providers.
Results: After 2 years of follow-up, mean life-years were 1.78 in the endovascular repair group and 1.74 in the open repair group (difference, 0.04; 95% confidence interval [CI], −0.03 to 0.09; P = .29). Mean QALYs were 1.462 in the endovascular group and 1.461 in the open group (difference adjusting for baseline EQ-5D score, 0.006; 95% CI, −0.038 to 0.052; P = .78). Mean graft costs were higher in the endovascular group ($14,052 vs $1363; $P < .001$), but length of stay was shorter (5.0 vs 10.5 days; $P < .001$), resulting in a lower mean cost of the hospital admission for the AAA procedure in the endovascular repair group of $37,068 vs $42,970 (difference, −$5901; 95% CI, −$12,135 to −$821; P = .04). After 2 years, total health care costs remained lower in the endovascular group, but the difference was no longer significant (−$5019; 95% CI, −$16,720 to $4928; P = .35). The probability of endovascular repair being less costly and more effective was 70.9% for life-years and 51.4% for QALYs.
Conclusions: In this multicenter randomized trial, endovascular AAA repair resulted in lower cost and better survival than open repair after the initial hospitalization for repair; but after 2 years, survival, quality of life, and costs were not significantly different between the two treatments.

Patients with chronic obstructive pulmonary disease have shorter survival but superior endovascular outcomes after endovascular aneurysm repair

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Objective: This study determined the effect of pulmonary disease on outcomes after endovascular abdominal (EVAR) and endovascular thoracoabdominal aortic aneurysm (eTAAA) repair.
Methods: A prospective study of high-risk patients undergoing EVAR and eTAAA repair between 1998 and 2009 was used to contrast clinical and endovascular outcomes between patients with (group 1) and without (group 2) chronic obstructive pulmonary disease (COPD). COPD patients were classified in accordance with the severity of their pulmonary disease using the Global Initiative for Chronic Obstructive Lung Disease criteria. Survival, morphologic changes, and complications were assessed using Cox models and life-table analyses. The cause and timing of deaths between the groups was compared.
Results: Of 905 patients analyzed, 289 (32%) had COPD (group 1) and the remaining patients (group 2) did not have COPD. EVAR was performed in 334 patients (37%), and fenestrated or branched devices were used in the remaining 571 (63%). Group 1 patients were younger (73.5 ± 6.7 vs 75.6 ± 8.2 years), had a better glomerular filtration rate (67.8 ± 25.8 vs 61.0 ± 23.3 mL/min/1.73 m^2), had higher hematocrits (41.6 ± 5.0 vs 40.5 ± 4.6), and had more extensive aneurysms. Mean follow-up was 39.5 ± 30.9 months. Early (3% vs 3%) and late (2% vs 1%) aneurysm-related deaths were similar between the two groups. Survival in group 1 depended on the severity of disease. Survival in patients with Global Initiative for Chronic Obstructive Lung Disease classification I and II was similar to group 2. Those with classifications III and IV demonstrated lower survival rates. Relevant pulmonary function test variables included a lower forced expiratory volume in 1 second and forced expiratory flow in the middle 50%, which were associated with decreased survival. Surrogate endovascular outcome analyses demonstrated that group 1 patients had fewer endoleaks (20% vs 25%; $P = .05$) and more rapid sac shrinkage rate (1.66 mm/y difference; $P < .001$).
Conclusions: The perioperative risk of death between COPD patients and non-COPD patients is eliminated when endovascular techniques are used. Long-term survival in COPD patients is most strongly related to the severity of their disease, and forced expiratory volume in 1 second and forced expiratory flow in the middle 50% are reasonable indicators of poor long-term outcomes. Morphologic changes after EVAR and eTAAA repair are more favorable in COPD patients, with a lower endoleak rate and faster sac shrinkage.

Estimating the risk of solid organ malignancy in patients undergoing routine computed tomography scans after endovascular aneurysm repair

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Objective: Computed tomography (CT) scans are routinely used for graft surveillance in patients who have had endovascular repair (EVAR) of an abdominal aortic aneurysm. There is a growing concern for cancers associated with inadvertent use of CT scans. We report the estimated risk of radiation associated solid organ malignancy caused by routine surveillance CT after EVAR using the Biological Effects of Ionizing Radiation (BEIR VII)

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model created by U.S. National Institute of Science and National Research Council.

Methods: Our study estimated the excess relative risk (ERR) of a patient acquiring a solid organ malignancy secondary to radiation exposure from postoperative EVAR surveillance CT imaging. The radiation dose was calculated in sieverts (Sv). The ERR of solid organ malignancy, as given by the BEIR VII model, is = β_s D exp $\{\gamma e^*\}$ $(a/60)^{\eta}$, where β_s, γ, and η are data-derived parameters, e is age at exposure, and e^* = (e-30)/10 for $e < 30$ and zero for $e \geq 30$, a is attained age, and D is dose in sieverts. Dose-weighted ERRs were calculated to allow a comparison of malignancy risk when using a CT at all time points (model 1: 0, 1, 6, 12, and 18 months, 2, 3, and 4 years, and yearly thereafter) vs replacing the CT scan with two other models (model 2: CT once in 3 years) and (model 3: CT once in 5 years). The risk was stratified by age groups, sex, and use of two different radiation doses (15 or 31 mSv) per CT scan. Statistical analysis used the paired t test.

Results: There were significant differences between the ERR of solid organ malignancy in those patients who would undergo surveillance CTs at all time points vs those whose surveillance consisted of alternative modalities at some time points ($P < .0001$). The cumulative ERR of cancer from radiation was higher in those exposed to contrast-enhanced CT scans, younger people, with highest in the group aged 50 to 55 years (ERR, 0.43), and lowest in patients aged ≥80 years (ERR, 0.10).

Conclusions: Patients undergoing routine CT scans for postoperative surveillance after EVAR are at risk for acquiring new solid organ malignancy due to radiation exposure. The risk is higher in young patients, women, and those exposed to multiple contrast-enhanced CT scans. Our analysis questions the need for routine surveillance CT scans after EVAR in the absence of endoleaks or a change in aneurysm morphology, based on an increased malignancy risk.

Direct percutaneous sac injection for postoperative endoleak treatment after endovascular aortic aneurysm repair

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Background: This study presents the short-term and midterm results of direct percutaneous sac injection (DPSI) for postoperative endoleak treatment after endovascular aortic aneurysm repair (EVAR).

Methods: Between March 1994 and November 2011, EVAR was performed in 986 patients. The median follow-up was 63 ± 45 months (range, 0-211 months). A retrospective analysis was performed. DPSI was used in 21 patients for 19 type II endoleaks and two endoleaks of undefined origin (EOUO), of which 12 (57%) were after failure of a previous endovascular treatment attempt.

Results: DPSI using thrombin (n = 16), coils (n = 7), gelfoam (n = 6), or glue (n = 3), or a combination, was technically feasible in all patients. Saccography during DPSI revealed a previously undetected type I endoleak in three patients. Immediate DPSI success was achieved in 16 of 18 procedures (88.9%), with two complications. Glue incidentally intravasated in the inferior vena cava, causing a clinically nonsignificant subsegmental pulmonary artery embolism in one patient, and the temporary development of a type III endoleak, possibly from graft puncture, in another. During a median follow-up of 39 months (interquartile range, 13-88 months) after DPSI, recurrent endoleaks were observed in nine patients (50.0%), one type I endoleak due to graft migration, five type II endoleaks, and three EOUO. The occurrence of a re-endoleak during follow-up was significantly associated with dual antiplatelet medication (0% in patients without re-endoleak vs 44.4% in patients with re-endoleak; $P = .023$) and with a nonsignificant trend for the use of aspirin alone (33.3% in patients without re-endoleak vs 80% in patients with re-endoleak; $P = .094$). Re-endoleak occurred in 33.3% of the patients without antiplatelet medication and in 100% of patients with dual-antiplatelet medication ($P = .026$). Thrombin was used as the sole embolic agent during the initial DPSI in all patients with dual-antiplatelet therapy. No other factor was significantly associated with re-endoleaks. Reintervention was deemed necessary in six patients within a median of 10 months (interquartile range, 4-16 months) after DPSI, including six additional DPSI treatments in four patients with type II re-endoleaks, cuff placements in one type I endoleak, and endograft relining in one EOUO.

Conclusions: This initial experience suggests that DPSI is feasible as a technique for endoleak treatment after EVAR. However, complications and endoleak recurrence remain a concern. The role of antiplatelet therapy and different embolic agents on long-term embolization success needs to be studied in more detail.

Impact of preoperative embolization on outcomes of carotid body tumor resections

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Objectives: This study assessed neurovascular complications in the surgical management of carotid body tumors (CBTs), with emphasis on those treated with and without preoperative embolization.

Methods: We reviewed the clinical data of all consecutive patients with CBTs treated by surgical resection at our institution from 1985 to 2010. Outcomes were compared between Shamblin class II and III CBTs treated with preoperative embolization (EMB group) and with no preoperative embolization (NEMB group).

Results: A total of 131 patients (80 women, 51 men), who were aged 48 years (range, 16-84 years), had resection of 144 CBTs and 12 concurrent cervical paragangliomas. This included 18 patients who had bilateral resections and 29 with familial CBTs. Succinate dehydrogenase (SDHx) mutations were confirmed in 17 patients. Mean tumor volume was 20.5 cm^3 (range, 0.8-101.3 cm^3), and there were two biochemically active CBTs (1%). There were 71 Shamblin II and 33 Shamblin III. The EMB group underwent 33 CBT resections, and the NEMB group underwent 71. There were more patients in the EMB group with bilateral (48% vs 22%; $P = .01$) and familial (34% vs 14%; $P = .01$) CBT; otherwise, patient demographics, Shamblin class, and tumor diameter and volumes were similar. No strokes or other major complications occurred after preoperative embolization with polyvinyl alcohol particles 1 day before surgery. The EMB group required less extensive procedures (simple excision in 97% vs 82%, $P = .03$; internal carotid artery clamping in 15% vs 37%, $P = .04$) and had less blood loss (mean estimated blood loss, 263 vs 599 mL; $P = .002$) than the NEMB group. However, there were no significant differences in operative time (250 vs 265 minutes; $P = .49$), temporary cranial nerve injury (52% vs 38%; $P = .21$), clinically apparent cranial nerve deficits after 1 year (12% vs 7%; $P = .46$), deaths (0% vs 0%; $P > .99$), stroke (0% vs 1%; $P > .99$), or postoperative length of stay (4.1 vs 4.2 days; $P = .91$).

Conclusions: Large CBTs can be resected safely with or without preoperative embolization. Preoperative embolization may simplify the conduct of the operation and reduce blood loss but does not decrease rates of cranial nerve injury, although most are temporary.

Risk factors for clinical failure after stent graft treatment for femoropopliteal occlusive disease

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Objective: Optimal selection of a revascularization strategy in femoropopliteal occlusive disease (FPOD) remains controversial. Among endovascular treatment options for FPOD, covered stent placement has become increasingly used. We sought to examine the influence of clinical, anatomic, and device-related characteristics on the clinical performance of these devices.

Methods: This was a retrospective, single-center study of consecutively treated limbs that underwent Viabahn (W. L. Gore, Flagstaff, Ariz) stent graft placement for FPOD from 2005 to 2010. Clinical, anatomic, and device-related characteristics were obtained from review of medical records and angiograms. End points were occurrence of any reintervention, major adverse limb event (eg, major amputation, thrombolysis/thrombectomy, or open bypass surgery), or thrombolysis/thrombectomy treatment alone. Univariate predictors were calculated and multivariate models constructed for each clinical end point using Cox proportional hazards models.

Results: The study cohort included 87 limbs in 77 unique patients, with a median follow-up time of 382 days. The indication for intervention was claudication in 56%. In 25 cases (29%), the index procedure was a secondary intervention for FPOD, including treatment of in-stent restenosis in 22 cases (25%). Lesions treated included 45% TransAtlantic Inter-Society Consensus (TASC) II D and 58% chronic total occlusions. The observed Kaplan-Meier 1-year event rates for reintervention, major adverse limb event (MALE), and thrombolysis were 43%, 28%, and 17%, respectively. MALE occurred in 18 patients, nine of whom presented with acute limb ischemia; no patient underwent major amputation. Univariate predictors of negative outcomes included lack of dual-antiplatelet usage, advanced TASC II classification, smaller implant diameter, increased number of devices used, longer total implant length, and coverage of a patent distal collateral vessel. Multivariate analysis demonstrated that the presence of dual-antiplatelet usage was protective against all three outcomes, 5-mm device diameter was a risk factor for both reintervention and MALE, and the use of multiple devices and distal collateral coverage were significant risk factors for thrombolysis events.
Conclusions: Reintervention is common in the first year after Viabahn placement for FPOD, with more than half of the events being a MALE. Procedural factors such as antiplatelet therapy, stent graft diameter, implant length/number, and distal collateral coverage are strongly associated with adverse clinical outcomes. These factors should be carefully considered to optimize patient selection and intraoperative decision making for this procedure.

Influence of high-heeled shoes on venous function in young women

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Background: Walking with high-heeled shoes is a common cause of venous complaints such as pain, fatigue, and heavy-feeling legs. The aim of the study was to clarify the influence of high-heeled shoes on the venous return and test the hypothesis that women wearing different styles of high-heeled shoes present an impaired venous return when compared with their values when they are barefoot.
Methods: Thirty asymptomatic women (mean age, 26.4 years) wearing appropriately sized shoes were evaluated by air plethysmography (APG), a test that measures changes in air volume on a cuff placed on the calf, while they performed orthostatic flexion and extension foot movements and altered standing up and lying down. The test was repeated in four situations: barefoot (0 cm), medium heels (3.5 cm), stiletto high heels (7 cm), and platform high heels (7 cm). The APG values of venous filling index (VFI), ejection fraction (EF), and residual volume fraction (RVF) were divided into four groups according to heel height and compared by repeated-measures analysis of variance.
Results: RVF was increased in the groups wearing high heels (stiletto and platform) compared with the barefoot group ($P < .05$). RVF was increased in the medium-heel group (3.5 cm) compared with the barefoot group ($P < .05$), and despite the lack of statistical significance, the medium-heel group showed lower values of RVF compared with the two high-heel groups. The EF parameter followed the opposite tendency, showing higher values for the barefoot group compared with the other three groups ($P < .05$). Values for VFI were similar in the three situations evaluated.
Conclusions: High heels reduce muscle pump function, as demonstrated by reduced EF and increased RVF values. The continuous use of high heels tends to provoke venous hypertension in the lower limbs and may represent a causal factor of venous disease symptoms.

Critical analysis of renal duplex ultrasound parameters in detecting significant renal artery stenosis

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Background: Several published studies have reported differing results of renal duplex ultrasound (RDU) imaging in detecting significant renal artery stenosis (RAS) using different Doppler parameters. This study is the largest to date to compare RDU imaging vs angiography and assess various published Doppler criteria.
Methods: RDU imaging and angiography were both done in 313 patients (606 renal arteries). RAS was classified as normal, <60%, ≥60% to 99%, and occlusion. Main outcome measurements included renal peak systolic velocity (PSV), systolic renal-to-aortic ratio (RAR), end-diastolic velocity (EDV), and kidney lengths.
Results: The mean PSVs and RARs for normal, <60%, and ≥60% stenosis were 173, 236, and 324 cm/s ($P < .0001$), and 2.2, 2.9, and 4.5, respectively ($P < .0001$). The PSV cutoff value that provided the best overall accuracy for ≥60% stenosis was 285 cm/s, with a sensitivity, specificity, and overall accuracy of 67%, 90%, and 81%, respectively. The RAR cutoff value with the best overall accuracy for ≥60% stenosis was 3.7, with a sensitivity, specificity, and overall accuracy of 69%, 91%, and 82%, respectively. A PSV of ≥180 cm/s and RAR of ≥3.5 had a sensitivity, specificity, and overall accuracy of 72%, 81%, and 78% in detecting ≥60% stenosis. A PSV of ≥200 cm/s with an RAR of ≥3.5 had a sensitivity, specificity, and overall accuracy of 72%, 83%, and 78% in detecting ≥60% stenosis. A receiver operator characteristic (ROC) curve analysis showed that the PSV and RAR were better than the EDV in detecting ≥60% stenosis: PSV area under the curve (AUC) was 0.85 (95% confidence interval [CI], 0.81-0.88), EDV AUC was 0.71, and RAR AUC was 0.82 (PSV vs EDV, $P < .0001$; PSV vs RAR, $P = .075$; EDV vs RAR, $P < .0001$). A PSV of 285 cm/s or RAR of 3.7 alone were better than any combination of PSVs, EDVs, or RARs in detecting ≥60% stenosis. The mean kidney length was 10.4 cm in patients with ≥60% stenosis vs 11.0 cm in patients with <60% stenosis ($P < .0001$). Twelve percent of patients with ≥60% stenosis had a kidney length of ≤8.5 cm vs 4% in patients with <60% stenosis ($P = .0003$), and 5.6% (34 of 606) had accessory renal arteries on angiography, with six detected on RDU imaging. The presence of accessory renal arteries, solitary kidneys, or renal fibromuscular dysplasia had no influence on overall accuracy of using PSV values for detecting ≥60% stenosis.
Conclusions: A PSV of 285 cm/s or an RAR of 3.7 alone can be used in detecting ≥60% RAS. Previously published data must be validated in individual vascular laboratories.