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JVS ABSTRACTS

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Editors: Peter Gloviczki and Peter F. Lawrence

Selected Abstracts from the *Journal of Vascular Surgery*

Reporting standards for endovascular aortic repair of aneurysms involving the renal-mesenteric arteries

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Endovascular aortic aneurysm repair of complex aortic aneurysms requires incorporation of side branches using specially designed aortic stent grafts with fenestrations, directional branches, or parallel stent grafts. These techniques have been increasingly used and reported in the literature. The purpose of this document is to clarify and to update terminology, classification systems, measurement techniques, and end point definitions that are recommended for reports dealing with endovascular repair of complex abdominal and thoracoabdominal aortic aneurysms involving the renal and mesenteric arteries.

Society for Vascular Surgery clinical practice guidelines of thoracic endovascular aortic repair for descending thoracic aortic aneurysms

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Thoracic aortic diseases, including disease of the descending thoracic aorta (DTA), are significant causes of death in the United States. Open repair of the DTA is a physiologically impactful operation with relatively high rates of mortality, paraplegia, and renal failure. Thoracic endovascular aortic repair (TEVAR) has revolutionized treatment of the DTA and has largely supplanted open repair because of lower morbidity and mortality. These Society for Vascular Surgery Practice Guidelines are applicable to the use of TEVAR for descending thoracic aortic aneurysm (TAA) as well as for other rarer pathologic processes of the DTA. Management of aortic dissections and traumatic injuries will be discussed in separate Society for Vascular Surgery documents. In general, there is a lack of high-quality evidence across all TAA diseases, highlighting the need for better comparative effectiveness research. Yet, large single-center experiences, administrative databases, and meta-analyses have consistently reported beneficial effects of TEVAR over open repair, especially in the setting of rupture. Many of the strongest recommendations from this guideline focus on imaging before, during, or after TEVAR and include the following:

In patients considered at high risk for symptomatic TAA or acute aortic syndrome, we recommend urgent imaging, usually computed tomography angiography (CTA) because of its speed and ease of use for preoperative planning. Level of recommendation: Grade 1 (Strong), Quality of Evidence: B (Moderate).

If TEVAR is being considered, we recommend fine-cut ($\leq$0.25 mm) CTA of the entire aorta as well as of the iliac and femoral arteries. CTA of the head and neck is also needed to determine the anatomy of the vertebral arteries. Level of recommendation: Grade 1 (Strong), Quality of Evidence: A (High).

We recommend routine use of three-dimensional centerline reconstruction software for accurate case planning and execution in TEVAR. Level of recommendation: Grade 1 (Strong), Quality of Evidence: B (Moderate).

We recommend contrast-enhanced computed tomography scanning at 1 month and 12 months after TEVAR and then yearly for life, with consideration of more frequent imaging if an endoleak or other abnormality of concern is detected at 1 month. Level of recommendation: Grade 1 (Strong), Quality of Evidence: B (Moderate).

Finally, based on our review, in patients who could undergo either technique (within the criteria of the device's instructions for use), we recommend TEVAR as the preferred approach to treat elective DTA aneurysms, given its reduced morbidity and length of stay as well as short-term

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mortality. Level of recommendation: Grade 1 (Strong), Quality of Evidence: A (High).

Given the benefits of TEVAR, treatment using a minimally invasive approach is largely based on anatomic eligibility rather than on patient-specific factors, as is the case in open TAA repair. Thus, for isolated lesions of the DTA, TEVAR should be the primary method of repair in both the elective and emergent setting based on improved short-term and midterm mortality as well as decreased morbidity.

Anatomic feasibility of the investigational GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis (TAMBE), off-the-shelf multibranched endograft for the treatment of pararenal and thoracoabdominal aortic aneurysms

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Objective: The objective of this study was to evaluate the proportion of pararenal aortic aneurysms and thoracoabdominal aortic aneurysms (TAAAs) that could theoretically be treated with the investigational GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis (TAMBE; W. L. Gore & Associates, Flagstaff, Ariz) off-the-shelf multibranched endograft.

Methods: The preoperative computed tomography scans of patients with pararenal aortic aneurysms and TAAAs treated at a single institution between 2007 and 2017 were reviewed. This cohort included both open and endovascular repairs performed in either elective or urgent/emergent settings. These studies were included in a retrospective feasibility study to verify anatomic feasibility of the TAMBE graft (with four antegrade portals) employed within the manufacturer's investigational instructions for use during the U.S. pivotal trial. The patient cohort was divided into two groups: extended thoracoabdominal aneurysm (E-TAA)—extent I, II, and III TAAA; and limited pararenal and thoracoabdominal aneurysm (L-TAA)—pararenal aortic aneurysm and extent IV TAAA. The anatomic factors determining the overall theoretical feasibility were further divided into three groups: vascular access feasibility, aortic feasibility, and visceral vessel feasibility.

Results: Computed tomography scans of 227 patients with degenerative aneurysms were analyzed, 166 with E-TAA and 61 with L-TAA. In the L-TAA group, 49% of the cases could have been treated with the TAMBE endograft alone; access feasibility was 85%, aortic feasibility 74%, and visceral vessel feasibility 72%. In the E-TAA group, only 23% of the cases could have been treated with a TAMBE combined with a GORE CTAG proximal thoracic stent graft; access feasibility was 79%, aortic feasibility 48%, and visceral vessel feasibility 63%. The different feasibility rate was related to a difference in aortic feasibility between L-TAA and E-TAA (74% vs 48%; P = .0008) because of the lack of a dedicated tapered thoracic component.

Conclusions: The TAMBE multibranched endograft can theoretically be employed in half of an all-comers cohort of patients with degenerative L-TAA. Development of a dedicated tapered thoracic component is warranted to increase the feasibility for E-TAA, and comparative studies are required to investigate differences with other available off-the-shelf stent grafts.

Evaluating the prevalence of abdominal aortic aneurysms in the United States through a national screening database

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Objective: The U.S. Preventative Services Task Force guidelines for abdominal aortic aneurysm (AAA) screening are based mainly on studies of older Caucasian males from non-U.S. populations. This study was designed to analyze the findings of a large, all-inclusive AAA screening program in the United States.

Methods: Screening events were held nationally by a U.S. nonprofit organization between 2001 and 2017. AAA screening was offered regardless of risk profile. Participants filled out a demographics form with known comorbidities. Significant risk factors were determined using logistic regression with backward stepwise variable selection. Odds ratios (OR) are reported with 95% confidence intervals (CIs).

Results: A total of 9457 screened participants (47% male) were analyzed. The mean age was 67 $\pm$ 9 years with 40.8% between 65 and 75 years old. Most participants were Caucasian (83.4%), followed by African American (13.1%). Screened risk factors included hypertension (58.1%), hyperlipidemia (54.9%), smoking (52.0%), cardiac disease (29.2%), diabetes mellitus (18.4%), a family history of AAA (22.4%) or brain aneurysms (8.6%), and body mass index (26.9 $\pm$ 5.28). Overall, 267 participants (2.82%) were found to have an AAA ($>$3 cm). Those ages 65 to 75 had a prevalence of 2.98%. In a fully adjusted, multivariate logistic regression, there was an increased risk of AAA in males (OR, 3.24; 95% CI, 2.39-4.40), current smokers (OR, 3.28; 95% CI, 2.36-4.54), previous smokers (OR, 1.86; 95% CI, 1.41-2.47), cardiac disease (OR, 1.30; 95% CI, 1.01-1.68), family history of AAA (OR, 1.60; 95% CI, 1.20-2.14), and advancing age ($P < .0001$). Female ever smokers 65 to 75 years old had a prevalence of 1.7%. Male smokers 45 to 54 and 55 to 64 years old had a prevalence of 3.37% and 4.43%, respectively. There was an increased risk of AAA in females with morbid obesity (OR, 5.54; 95% CI, 1.34-22.83 in never smokers and OR, 5.61; 95% CI, 1.04-30.15 in smokers), female smokers with hypertension (OR, 3.22; 95% CI, 1.21-8.58), males with cardiac disease (OR, 2.06; 95% CI, 1.08-3.90 in never smokers and OR, 1.48; 95% CI, 1.05-2.09), male smokers with a family history of AAA (OR, 1.69; 95% CI, 1.61-2.46), and current smokers (OR, 6.33; 95% CI, 2.62-15.24 for females and OR, 2.50; 95% CI, 1.70-3.65 for males).

Conclusions: This study shows that there remain high-risk groups outside the current guidelines that would likely benefit from AAA screening. Risk factors for AAA include male gender, smoking, cardiac disease, family history of AAA, and advancing age. The most significant risk factor is current smoking status.

The benefit of deferred carotid revascularization in patients with moderate-severe disabling cerebral ischemic stroke

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Objective: Symptomatic carotid artery stenosis needs revascularization within 2 weeks by carotid endarterectomy (CEA) to reduce the risk of symptom recurrence; however, the optimal timing of intervention is yet to be defined in patients with large-volume cerebral ischemic lesion (LVCIL) and modified Rankin scale (mRS) score $\geq$3. The aim of this study was to determine the most appropriate timing for CEA in patients with a recent stroke and LVCIL.

Methods: Data from patients with symptomatic carotid stenosis with LVCIL and mRS score of 3 or 4 from 2007 to 2017 were considered. Patients were submitted to CEA if they had a stable clinical condition and life expectancy $>$1 year. LVCIL was defined as a cerebral ischemic lesion of volume $>$4000 mm^3. Perioperative stroke and death were evaluated by stratifying for timing of CEA by χ^2 test and multiple logistic regression. Patients with similar characteristics (LVCIL and mRS score of 3 or 4) unfit for CEA served as the control group for recurrence of stroke at 1-year follow-up.

Results: In an 11-year period, of a total 4020 CEAs, 126 (2.9%) were performed in patients with a moderate stroke and LVCIL occurring in the same admission. The patients' median age was 69 years (interquartile range [IQR], 10 years); 72% (91) were male, with mRS score of 3 (IQR, 1) and LVCIL volume of 20,000 mm^3 (IQR, 47,000 mm^3). The median time elapsed from symptoms to CEA was 7 weeks (IQR, 8 weeks). Overall perioperative stroke/death was 7.3% (eight strokes and one death). By selective timing evaluation of the postoperative events, CEA performed within 4 weeks was associated with a significantly higher rate of stroke/death compared with patients operated on after 4 weeks: 11.9% (8/67) vs 1.7% (1/59; P = .03). By logistic regression, CEA within 4 weeks was an independent (from sex, cerebral ischemic lesion volume, dyslipidemia, and carotid stenosis) predictor of postoperative stroke/death (odds ratio, 8.2; 95% confidence interval, 1.01-73). In the same period, 101 patients were considered unfit for CEA for dementia (n = 22), severe comorbidities (n = 55), or short ($<$1-year) life expectancy (n = 24), and 43 (43%) survived at 1 year. At 1 year, the perioperative/recurrent stroke after CEA vs patients unfit for CEA was similar (6.2% vs 13.9%; P = .11), but CEA performed after 4 weeks led to significantly lower perioperative/recurrent stroke (1.7% vs 13.9%; P = .02).

Conclusions: The surgical risk of CEA in patients with a recent moderate-severe ischemic stroke and LVCIL is high. However, if the intervention is delayed $>$4 weeks, its benefit seems significant.

Outcomes of rotational atherectomy in complex lesions of the superficial femoral artery

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Background: The effectiveness of rotational atherectomy in the treatment of complex superficial femoral artery (SFA) lesions remains poorly defined. Outcomes of SFA lesions treated with rotational atherectomy were analyzed.

Methods: This retrospective review assessed all patients who underwent rotational atherectomy of the SFA at a single institution between 2015 and 2018. The data of all patients were deidentified, and the study was approved by the Institutional Review Board. Informed consent was not obtained for this retrospective analysis. Main outcomes were Kaplan-Meier primary patency rate, freedom from major amputation, and 2-year survival rate. The effect of drug-coated balloon angioplasty (DCBA) on patency and time to death was investigated with univariate regression. The safety profile for atherectomy and DCBA was assessed by the 30-day incidence of major amputation and all-cause mortality.

Results: Fifty-three patients (mean age, 70.2 $\pm$ 9.8 years; 73% male; 65% critical limb-threatening ischemia; 47 [90%] current or former smokers; 7 [13%] with prior failed ipsilateral endovascular intervention) underwent rotational atherectomy (Jetstream; Boston Scientific, Marlborough, Mass) with mean follow-up of 543 days. Forty-six (87%) patients underwent DCBA (Lutonix; BD Bard, Covington, Ga) after atherectomy. Mean lesion length was 13.2 $\pm$ 9.0 cm. Thirty-one (58%) lesions were TransAtlantic Inter-Society Consensus C or D class. At 1-month follow-up, 39 of 45 (87%) patients experienced improvement in symptoms and Rutherford class. An improvement in ankle-brachial index was also noted in 13% of patients without improvement of symptoms, with no patients progressing to surgical bypass or major amputation. Mean ankle-brachial index increased from 0.54 $\pm$ 0.035 to 0.90 $\pm$ 0.031 at 1 month after intervention (P $<$ .001) and remained constant out to 18 months. Mean toe pressure increased from 36 $\pm$ 3.8 mm Hg to 67 $\pm$ 4.5 mm Hg at 1 month after intervention (P $<$ .001) and remained constant out to 18 months. Kaplan-Meier primary patency rate was 75% (95% confidence interval, 61%-85%) at 12 months and 65% (51%-77%) at 24 months. There was a trend toward improved primary patency after adjunctive DCBA compared with plain balloon

angioplasty at 1 year (75% vs 43%; *P* = .1082). There was no significant difference in mortality between adjunctive DCBA and plain balloon angioplasty at 2 years (11% vs 0%). The 2-year incidence of major amputation in critical limb-threatening ischemia patients was 3.9% (1.2%-6.5%). One patient died and none underwent amputation within 30 days.

Conclusions: Rotational atherectomy with adjunctive DCBA of long SFA lesions has excellent long-term patency. Two-year major amputation and mortality rates are low, and the technique has an exceptional safety profile.

Selected Abstracts from the *Journal of Vascular Surgery: Venous and Lymphatic Disorders*

Classification and treatment of endothermal heat-induced thrombosis: Recommendations from the American Venous Forum and the Society for Vascular Surgery

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The American Venous Forum (AVF) and the Society for Vascular Surgery set forth these guidelines for the management of endothermal heat-induced thrombosis (EHIT). The guidelines serve to compile the body of literature on EHIT and to put forth evidence-based recommendations. The guidelines are divided into the following categories: classification of EHIT, risk factors and prevention, and treatment of EHIT. One major feature is to standardize the reporting under one classification system. The Kabnick and Lawrence classification systems are now combined into the AVF EHIT classification system. The novel classification system affords standardization in reporting but also allows continued combined evaluation with the current body of literature. Recommendations codify the use of duplex ultrasound for the diagnosis of EHIT. Risk factor assessments and methods of prevention including mechanical prophylaxis, chemical prophylaxis, and ablation distance are discussed. Treatment guidelines are tailored to the AVF EHIT class (ie, I, II, III, IV). Reference is made to the use of surveillance, antiplatelet therapy, and anticoagulants as deemed indicated, and the recommendations incorporate the use of the novel direct oral anticoagulants. Last, EHIT management as it relates to the great and small saphenous veins is discussed.

Randomized clinical trial of radiofrequency-induced thermotherapy combined with transilluminated powered phlebectomy versus high ligation and stripping for the treatment of lower limb varicose veins

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Objective: The objective of this study was to evaluate the efficacy and safety of radiofrequency-induced thermotherapy (RFiTT) combined with transilluminated powered phlebectomy (TIPP) in the treatment of lower limb varicose veins (VVs) in comparison with high ligation and stripping (HLS) combined with TIPP.

Methods: The patients with lower limb VVs were randomly assigned to RFiTT combined with TIPP or HLS combined with TIPP. The primary end point was total closure rate of the great saphenous vein at 12 months. Secondary end points included Venous Clinical Severity Score and 14-item Chronic Venous Insufficiency Questionnaire score changes at 12 months and perioperative complications.

Results: The total closure rate of the great saphenous vein at 12 months was slightly lower in the RFiTT group (90.9% [90/99]) than in the HLS group (97.0% [98/101]) but not statistically significant (χ^2 = 0.068; *P* = .08). Operation time, intraoperative blood loss, duration in hospital, duration in bed, and resumption of activities were statistically significantly better with RFiTT than with HLS. There were no significant differences between the groups in deep venous thrombosis, phlebitis, hematomas, pain, and infection. However, skin pigmentation and paresthesia were statistically significantly better with RFiTT than with HLS. At 12 months, both groups showed similar improvement from baseline in Venous Clinical Severity Score (1.28 $\pm$ 0.57 in the RFiTT group vs 1.33 $\pm$ 0.61 in the HLS group) and 14-item Chronic Venous Insufficiency Questionnaire score (67.32 $\pm$ 1.29 in the RFiTT group vs 67.45 $\pm$ 1.32 in the HLS group); however, neither group was superior to the other.

Conclusions: RFiTT combined with TIPP is an effective treatment method for lower limb VVs and had a more satisfactory clinical outcome in surgical data, skin pigmentation, and paresthesia than HLS at the 12-month follow-up.